No. 91-248

IN THE

Supreme Court of the United States

October Term, 1991

KAREN ENRIGHT, an Infant under the age 14 years old, by her mother and natural guardian, PATRICIA ENRIGHT,

Petitioner,

PATRICIA ENRIGHT, Individually, and EARL ENRIGHT, Individually,

Plaintiffs,

against

ELI LILLY & COMPANY, E. R. SQUIBB & SONS, INC., ABBOTT LABORATORIES, THE UPJOHN COMPANY, MERCK & COMPANY, INC., and RXDC, INC., formerly known as REXALL CORPORATION, formerly known as REXALL DRUG COMPANY,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE COURT OF APPEALS OF THE STATE OF NEW YORK

PETITION FOR A WRIT OF CERTIORARI

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NYC 212-732-6978 Westchester 914-681-1322 Long Island 516-222-0221
(6707—LC4-158)

Question Presented.

1. Did the New York State Court of Appeals deny to infant Karen Enright equal protection and due process of law by depriving her of her constitutional right of access to the New York courts, when it arbitrarily excluded her (a victim of DES-related injuries) from the class of persons injured by the drug diethylstilbest (DES) which the state legislature in enacting remedial legislation had found was entitled to recover for its damage.

List of Parties.

The parties involved in the case before this court are as follows:

Plaintiffs-respondents in the Court of Appeals and petitioner herein	Karen Enright, an infant under the age of 14 years old, by her mother and natural guardian, Patricia Enright
Plaintiff-respondent in the Court of Appeals	Patricia Enright
Plaintiff-respondent in the Court of Appeals	Earl Enright
Defendants-appellants in the Court of Appeals and respondents herein	Eli Lilly & Company E.R. Squibb & Sons, Inc. Abbott Laboratories The Upjohn Company- Merck & Company, Inc. Rexall Drug Company

Table of Contents.

Page

TABLE OF CONTENTS TO APPENDIX.

TABLE OF AUTHORITIES.

CASES:

Page

Page

STATUTES:

Page

IN THE

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OCTOBER TERM, 1991.

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Opinions Below.

The opinion of the New York Court of Appeals is reported as *Enright v. Eli Lilly & Company* at 77 NY2d 377, 568 NYS2d 550 (1991) and is reprinted in the Appendix to this Petition at pages 1b-19b. The opinions of the lower courts are reported as *Enright v. Eli Lilly & Company,* at 141 Misc2d 194, 533 NYS2d 224 (Sup.Ct. Chenango Co. 1988) (App. pp. 1d-36d), modified and affirmed, 155 AD2d 64, 553 NYS2d 494 (3d Dept. 1990) (App. pp 1c-20c).

Jurisdiction.

The judgment of the New York State Court of Appeals was entered February 19, 1991. A rehearing was sought on, *inter alia,* constitutional grounds, and by order entered May 9, 1991 the New York State Court of Appeals denied the motion and thereby implicitly rejected petitioner's federal constitutional claims. This Court has certiorari jurisdiction under 28 U.S.C. §1257(a).

Constitutional and Statutory Provisions Involved.

The Fourteenth Amendment to the United States Constitution provides in pertinent part:

> "No State . . . shall . . . deprive any person of life, liberty or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."

Section 2 of chapter 682 of the 1986 Laws of New York provides in pertinent part:

> "§214-c [of the New York Civil Practice Law & Rules (CPLR)] certain actions to be commenced within three years of discovery

1. In this section: "exposure" means direct or indirect exposure by absorption, contact, ingestion, inhalation or injection.

2. Notwithstanding the provision of section 214, the three year period within which an action to recover damages for personal injury or injury to property caused by the latent effect of exposure to any substance or combination of substances, in any form, upon or with the body or upon or within property must be commenced shall be computed from the date of discovery of the injury by the plaintiff or from the date when through the exercise or reasonable diligence such injury should have been discovered by the plaintiff, whichever is earlier.

3. For the purposes of sections fifty-e and fifty-i of the general municipal law, section thirty-eight hundred thirteen of the education law and the provisions of any general, special or local law or charter requiring as a condition precedent to commencement of an action or special proceeding that a notice of claim be filed or presented within a specified period of time after claim or action accrued, a claim or action for personal injury or injury to property caused by the latent effects of exposure to any substance or combination of substance, in any form, upon or within the body or upon or within property shall be deemed to have accrued on the date of discovery of the injury by the plaintiff or on the date when through the exercise of reasonable diligence the injury should have been discovered whichever is earlier.

4. Notwithstanding the provisions of subdivisions two and three of this section, where the discovery of the cause of the injury is alleged to have occurred

less than five years after discovery of the injury or when with reasonable diligence such injury should have been discovered, whichever is earlier, an action may be commenced or a claim filed within one year of such discovery of the cause of the injury; provided, however, if any such action is commenced or claim filed after the period in which it would otherwise have been authorized pursuant to subdivision two or three of this section the plaintiff or claimant shall be required to allege and prove that technical, scientific or medical knowledge and information sufficient to ascertain the cause of his injury had not been discovered, identified or determined prior to the expiration of the period within which the action or claim would have been authorized and that he has otherwise satisfied the requirements of subdivisions two and three of this section.

* * *

6. This section shall be applicable to acts, omissions or failures occurring prior to, on or after July first, nineteen hundred eighty-six, except that this section shall not be applicable to any act, omission or failure:

(a) which occurred prior to July first, nineteen hundred eighty-six, and

(b) which caused or contributed to an injury that either was discovered or through the exercise of reasonable diligence would have been discovered prior to such date, and

(c) an action for which was or would have been barred because the applicable period of limitation had expired prior to such date."

Section 4 of chapter 682 of the 1986 Laws of New York provides in pertinent part:

> "Notwithstanding any other provision of law . . . every action for personal injury, injury to property or death caused by the latent effects of exposure to diethystibestrol, tungsten-carbide, asbestos, chloradane or polyvinylchloride upon or within the body or upon or within property which is barred as of the effective date of this act or which was dismissed prior to the effective date of this act solely because the applicable period of limitations has or had expired is hereby revived and an action thereon may be commenced provided such action is commenced within one year from the effective date [July 30, 1986] of this act [L. 1986, c. 682]. . . ."

Introduction

The issue in this case is whether a state court, in applying a state statute, can radically revise, or create exceptions to a state legislative plan which on its face is constitutional, and through such "judicial legislation" deprive an individual of due process and equal protection of those laws enacted in accordance with that legislative scheme. Pursuant to the decision of the court below the petitioner Karen Enright, a victim of the drug DES, is barred from recovering for her DES-related injuries under a state statute which provides access to the courts to all those injured by either direct or indirect exposure to DES. The court below held that by allowing petitioner—who is ostensibly part of the class of persons established by the State Legislature to be entitled to recover for DES-related injuries—to maintain her action under the state statute, such might, *inter alia,* cause a flood of lawsuits, and perhaps dissuade drug companies from marketing beneficial drugs. The court thus went on to reason, with these "public policy" considerations as a back-

drop, that since petitioner had been damaged due to defects in her mother's reproductive system caused by her mother's exposure to DES, and not by her own direct contact with the drug, such was a sufficient, rational basis for a new, discriminatory sub-class of victims—a sub-class that, the court held, was not entitled to recover for their DES-caused damages under the state's legislative plan.

The Legislature, however, never so limited the class of victims entitled to recover to only those directly contacting the drug, as opposed to those damaged by indirect exposure to DES. Indeed, under the legislative plan, "exposure" was explicitly defined to mean direct or indirect exposure upon or within the body. The Legislature's intention, obviously, was to include those persons in petitioner's category of plaintiffs in the class of victims afforded a means of recovering by the Toxic Torts bill (as the legislative plan is known), not to exclude them from the class of victims entitled to a remedy under the state's legislative scheme.

Substantial separation of powers and due process and equal protection questions are thus raised by the impermissible "judicial legislation" involved here. That judicial legislation carves out as ineligible to recover for their DES-caused injuries, from those victims of DES the State Legislature decided *were* entitled to recover for their DES-caused damages, a sub-class of DES victims, which has no rational basis.

Statement of the Case

A. DES and the Litigation of DES Claims.

DES (diethylstilbestrol) is a powerful synthetic substance that duplicates the activity of estrogen, a female sex hormone naturally present in women and, in lesser amounts, in men. It was first synthesized by British researchers in 1937,

but was never patented. As a result, it was available for production and marketing to any pharmaceutical manufacturer who obtained Federal Food and Drug Administration (FDA) approval. See *Bichler v. Eli Lilly and Co.*, 55 NY2d 571, 576 (1982).

Compared to natural estrogens, DES is inexpensive and easy to produce. Instead of requiring injections, it can be taken orally. DES was accordingly regarded by producers as an attractive product; "a revolutionary breakthrough in biomedical science." *Tidler v. Eli Lilly & Co.*, 851 F2d 418, 420 (D.C. Cir 1988). It made "estrogen therapy available for the first time to all women." *Ryan v. Eli Lilly & Co.*, 514 F. Supp. 1004, 1009 (D.S.C. 1982).

It was first approved for use in the United States in 1941. In that year, twelve pharmaceutical manufacturers, including Eli Lilly & Company, submitted separate, new drug applications (NDAs) to the FDA requesting approval of the marketing of DES for the treatment of vaginitis, engorgement of the breasts, excessive menstrual bleeding and symptoms of menopause. See *Bichler*, 55 NY2d at 576. Three years later the FDA approved several additional NDAs for use of DES in treating cancer of the prostrate in males. DES continues to be used to treat some of these non-pregnancy-related medical problems today. *Bichler*, 55 NY2d at 576; *Lyons v. Premo Pharmaceutical Labs, Inc.*, 170 NJ Super 183, 406 A2d 185, 189-190 (1979).

In 1947 the FDA approved DES for the treatment of human miscarriage. By 1951 the FDA had concluded that DES was generally safe for pregnancy use and stopped requiring the filing of NDAs when new manufacturers sought to produce the drug for this purpose. *Hymowitz v. Eli Lilly and Company*, 73 NY2d 487, 502, 541 NYS2d (1989); *Ryan*, 514 F. Supp. at 1011.

DES was widely prescribed for preventing miscarriages. Some 200-300 suppliers distributed products containing generic DES as an active ingredient. See *Zafft v. Eli Lilly & Co.*, 676 SW2d 241, 243 (Mo 1984). It was taken by an estimated 1.5 to 3 million pregnant women during the period 1947 to 1971. See *Sindell v. Abbott Laboratories*, 26 Cal 3d 588, 163 Cal Reptr. 132, 607 P.2d 924, 927, cert. denied, 449 US 912 (1980); *Bichler*, 55 NY2d at 577.

In 1971 the FDA banned the use of DES as a miscarriage preventative, when studies showed the harmful latent effects of DES upon the offspring of mothers who took the drug. Specifically, tests established that DES caused vaginal adenocarcinoma, a form of cancer and adenosis, a precancerous vaginal or cervical growth. *Hymowitz*, 73 NY2d at 503.

Between 1971 and 1981 the link between prenatal DES exposure and the later development in female offspring of clear cell cervical or vaginal adenocarcinoma, previously a rare disease involving cancerous growth in glandular tissue, was unquestionably confirmed. *Bichler*, 55 NY2d at 577.

B. The New York Toxic Torts Discovery Statute of Limitations and "Revival Statute."

In 1986 the New York State Legislature enacted, in accordance with a legislative scheme known as the Toxic Torts bill, a new secton of the Civil Practice Law and Rules (CPLR) which expanded the time limits for tort actions (other than medical or dental malpractice claims) based on direct or indirect exposure to several specifically identified harmful substances, including the drug DES. See Act of July 30, 1986, ch 682, §2 1986 NY Laws 1567 (see pp. 2-3 *supra*).

The statute applies to *all* actions for personal injury or wrongful death, or for injury to property, arising out of circumstances involving "the latent effects of exposure to any substance or combination of substances, in any form, upon or within the body or upon or within property" (except medical or dental malpractice claims). Thus, the instrumentality may be a drug, chemical, particulate, device or even machine that emits harmful radiation. The term "exposure" is defined broadly in the statute to include "absorption, contact, ingestion, inhalation or injection," *either directly or indirectly.*

This statute was part of New York Governor Cuomo's Program Toxic Torts bill and was adopted for the express purpose of remedying the injustice of denying any right to judicial relief to persons suffering from the latent effects of injuries from DES and other specifically named harmful substances. See New York Laws of 1986, ch 682. In signing the Toxic Torts bill into law, the Governor noted that "this measure * * * remedies a fundamental injustice in the laws of our state which has deprived persons suffering from exposure to toxic or harmful substances from having an opportunity to present their case in court [,]" that "[t]his measure remedies the injustices suffered by all of the currently known categories of victims of exposure * * * includ[ing] persons who have suffered serious injuries as a result of exposure to diethyistelbestrol (DES)," and that "this legislation culminates a multi-year effort by these victims to achieve this long overdue reform in our law. It is a victory for justice, and an example of democracy in action." Governor's Memorandum of Approval, 1986 McKinney's Session Laws of N.Y. at 3182-3184.

That same year, 1986, the New York Legislature passed as part of the Toxic Torts bill a special "revival" statute. See Act of July 30, 1986, ch 682 §4, 1986 N.Y. Laws 1567 (p. 5 *supra*). The statute revived *all* claims based on the "latent

effects of exposure" to DES and four other substances [asbestos, polyvinyl chloride (PVC), tungsten carbide and chlordane] that were otherwise barred by, or had been dismissed because of, the then extant statute of limitations.

The 1986 Toxic Torts legislation had been preceded in 1978 by a special statute designed to identify persons who had been "exposed to the potential hazards and afflictions of diethyistelbestrol." N.Y. Public Health Law §2500-C. In enacting this statute, the legislature made the specific findings that:

> "The effective identification, screening, diagnosis, care and treatment of persons who have taken diethylstilbestrol, commonly referred to as DES, or who have been exposed to DES prenatally is of paramount public importance.
>
> "Between nineteen hundred forty and nineteen hundred seventy, DES a synthetic estrogen-type hormone, was extensively administered to pregnant women threatened with miscarriage. Subsequently, a causal association was found between DES and an unusual type of cervical and vaginal cancer in the female offspring of those who took the drug during pregnancy. As a result of these findings, the use of DES during pregnancy has been discontinued, however, it is estimated that at lease one hundred thousand persons in New York state were exposed prenatally. *The vast majority of these persons are unaware of their exposure and have not been adequately screened for any malignant condition.*
>
> *"This problem in cancer control is likely to grow significantly over the next few years as exposed female off-spring reach reproductive age, the time*

when abnormalities become apparent." (Our emphasis)

C. The Proceedings Below and Presentation of Federal Questions.

Infant plaintiff Karen Enright, born August 9, 1981, alleged that her maternal grandmother ingested DES during a pregnancy which resulted in the birth of plaintiff Patricia Enright (Karen's mother) on January 29, 1960. Because of her *in utero* exposure to DES, Patricia Enright developed a variety of abnormalities and deformities in her reproductive system. As a result, several of her pregnancies terminated in spontaneous abortions and another resulted in the premature birth of plaintiff Karen Enright. The premature birth caused Karen to suffer from cerebral palsy and other disabilities.

After action herein was commenced by plaintiffs, and issue was joined, the defendants sought summary judgment dismissing the complaint. Defendants claimed the actions herein were barred by the statute of limitations.

The trial court granted the motions, in part, holding Karen Enright's injuries were not legally cognizable; but the Court rejected defendants' constitutional challenges to the Revival Statute. (App. p. 17d). Although the Appellate Division and the Court of Appeals did not expressly[1] address plaintiff's constitutional claims, they were presented in petitioner's motion for a rehearing in the Court of Appeals, which motion was denied (App. at p. 1a).

[1]The majority opinion discusses the "class" established by the Legislature through its enactment of the Toxic Torts legislation and the dissenter in the Court of Appeals (Judge Hancock) addressed plaintiff's constitutional claims by arguing that Karen Enright was improperly being treated by the Court in a manner different from that afforded other members of her *class* of DES victims—the very due process and equal protection arguments made by petitioner herein (see pp. 15-19, *infra*).

D. The Decision of the New York Court of Appeals.

Relying on a decision it had rendered in a garden-variety medical malpractice action, *Albala v. City of New York*, 54 NY2d 269, 445 NYS2d 108 (1981), the Court held that an injury to a mother which results in injuries to a later conceived child does not establish a cause of action in favor of the child against the original tortfeasor. It thus declined to recognize a cause of action on behalf of the plaintiff Karen Enright.

In so holding, the Court reasoned that the New York State Legislature, in passing the Toxic Torts bill, had not established DES plaintiffs as a favored *class* for whose benefit all traditional limitations on tort liability must give way. To the extent special rules had been fashioned, they were, the Court opined, a response to unique procedural barriers and problems of proof peculiar to DES litigation.

The Court went on to hold that the Legislature's enactment of the discovery statute of limitations for toxic torts was not intended to expand the basis of liability. Implicit in the statute's language, defining "exposure" to the named harmful substance as direct or indirect, was the notion that some direct contact with the substance was essential, the Court reasoned.

By limiting liability to those who either ingested the drug or were exposed to it *in utero,* the Court felt it would be confining liability within manageable limits. The Court feared that "the rippling effects of DES exposure *may* extend for generations" (our emphasis).

Limiting liability in this fashion, the majority concluded, would not unduly impair the deterrent purposes of tort liability because manufacturers would still remain amenable to suit by all those injured by actual physical *exposure*

to their product, "*a class* whose size is commensurate with the risk created" (our emphasis). It also noted that the tort system was not the only means of encouraging prescription drug safety; the Federal Food and Drug Administration has primary responsibility for that task.

In addition, as though the Legislature had not already expressed its clear intention to provide a remedy for all those injured by the effects of exposure to DES (to wit, the "class") in its enactment of the Toxic Torts legislation, the Court went on to hold that,

> "More importantly, however, is recognition that public policy favors the availability of prescription drugs even though most carry some risks (citations omitted). That is not to say that drug manufacturers should enjoy immunity from liability stemming from their failure to conduct adequate research and testing prior to the marketing of their products. They do not enjoy such immunity as evidenced by our recognition of liability in favor of those who have been injured by ingestion or *in utero* exposure to DES. But we are aware of the dangers of over-deterrence—the possibility that research will be discouraged or beneficial drugs withheld from the market. These dangers are magnified in this context, where we are asked to recognize a legal duty towards generations not yet conceived."

Finally, in answering the dissenter's accusation that the majority was usurping the legislative function by carving out a *class* of litigants who could not recover under the Toxic Torts legislation, the Court opined that, by preventing recovery in this case, it was simply adhering to established case law limits and therefore did not need further legislative action for it to limit liability as it had.

The dissenter (Judge Hancock) recognized that Karen Enright was one of a *class* of thousands of persons who have suffered devastating abnormalities and injuries from defendants' marketing of DES, and reasoned there was no basis in law or social policy, or any principled reason in justice and fairness that she should be singled out from other members of the *class* and not be permitted to prove her case. The policy of access to the courts from DES-related injuries had been established by the State Legislature and Karen Enright was not being treated equally under the law.

Judge Hancock continued by noting that the majority's statement that liability should stop at Karen's mother's generation because it "is commensurate with the risk" created was simply a statement of the Court's own policy determination as to where the risk—and hence, the liability—was to stop. Arguing that the majority had invaded the province of the Legislature by limiting the class created by it, the dissenter wrote:

> "If, as the majority apparently believes, there are economic and social considerations which require that there be some arbitrary cut-off point in cases of this kind, such a statute of repose could easily be engrafted on the Toxic Torts legislation which revived the long out-lawed dormant injury claims for DES and other substances (citations omitted). Suffice it to say, our legislature has not chosen to cut off the claims of injured persons in Karen Enright's generation."[2]

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[2]Judge Hancock again stressed the fact that Karen was not being provided the remedy afforded other members of her class when he held:

> . . . She is damaged no less than other victims of DES who make up the class. If they are permitted to recover, so should she be. To say that Karen Enright cannot recover is to abrogate

(Footnote continued on next page.)

Reasons for Granting the Writ.

The decision below violates fundamental principles of separation of powers, and basic tenets of equal protection and due process by arbitrarily and irrationally excluding petitioner from the class of injured persons afforded access to the courts by the New York State Legislature.

A state's development of its common law is, of course, limited by constitutional constraints. See, e.g., *New York Times Co. v. Sullivan,* 376 US 254, 265 (1963); *Brinberhoff-Faus Trust & Savings Co. v. Hill,* 281 US 673, 680 (1930). This "court must examine [the] state's chosen standard to determine whether it satisfies "the constitutional minimum of fundamental fairness." *Santosky v. Kramer,* 455 US 745, 756 n. 8 (1982) (citations omitted).

The rule adopted by the Court below amounts to judicial legislation which, on arbitrary and irrational grounds, unfairly excludes the petitioner herein from the class of injured persons afforded access to the courts, by the New York State Legislature, to recover damages for DES—related injuries. The ruling below is not merely an extension of established legal principles, but is an action of wholesale judicial legislation. See *Tidler,* 851 F2d at 422 (citation omitted); see also *Ryan,* 514 F. Supp at 1018. By the very nature of the judicial process, a court's ability to make legislative-like decisions is limited by its focus on the limited matter before it. In light of these inherent limita-

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(Footnote continued.)

> one of the most basic of all principles—that "like cases should be treated alike."
>
> * * *
>
> This decision . . . amounts to an exercise in . . . line-drawing reflecting social and economic policy choices which should be made not by Judges but by legislators.

tions, this Court should consider whether due process permits a state court to perform core legislative functions.

The separation of powers issue is presented in its most extreme form in this case. Here, the state legislature specifically found a need to provide a means of affording a remedy to *all persons* injured by direct or indirect exposure to DES (and other named harmful substances) and did so through the Governor's Toxic Torts bill.

The New York State Court of Appeals, in construing this otherwise constitutional statute, created its own sub-class, impermissibly based on "policy considerations" never expressed (and perhaps implicitly rejected) by the State Legislature, to wit, the "staggering implications" and "rippling effects" that upholding plaintiff-petitioner's claim *might* have; the theoretical *possibility* that research will be discouraged or beneficial drugs withheld from the market if petitioner were allowed to recover under the statute, and, using a cost-benefit analysis, the conclusion that generational line-drawing would be a proper limitation as commensurate with the risk created by the defendants' conduct.

There were, in fact, no studies conducted, commissioned or relied upon by the New York State Court of Appeals, nor any statistical data upon which it could properly draw in formulating the "policy" conclusions it did. The policy concerns the court used as a rationalization for excluding petitioner from that class of injured persons established by the Legislature as eligible for special consideration and treatment because of the nature of the injuries they had sustained, and of the substances causing them harm, were the Court's own policy determinations not those considered by the Legislature, the branch of government in which the power to legislate and thereby carry out public policy lies.

In addition, the Court's subcategorization of petitioner on generational grounds, so as to exclude her from the legislatively-created class to which she ostensibly belongs, was arbitrary and irrational and deprived petitioner of equal protection and due process of law.

This case thus presents the question of whether, under the due process clause, and the Fourteenth Amendment, affording equal protection of the laws, a state court may decide on public policy grounds that a particular sub-class of plaintiffs is less deserving than the class of plaintiffs (afforded a remedy by the Legislature), from which the sub-class is drawn, in a circumstance, such as this one, where the Legislature has seen fit *not* to create such a sub-class.

This Court has long recognized that a law may have no impermissible classification by its own terms, but it may be applied in such a manner as to create a new classification. The court will then test the law in its application to determine whether the new classification established is permissible. See e.g. *Yick Wo v. Hopkins,* 118 US 356, 65 Ct 1064, 302 LEd 220 (1886).

Moreover, if a court fails to open the judicial system to all persons within its jurisdiction on the same condition as to others in like circumstances, with like rules for the redress of wrongs, it deprives those excluded of equal protection. *Truax v. Corrigan,* 257 US 312, 66 LEd 254, 42 S Ct 124 (1921); *Southern R. Co. v. Greene,* 216 US400, 54 LEd 536, 30 S Ct 287 (1910); see also *Washington v. Davis,* 426 US 229, 48 LEd 2d 597, 96 S Ct 2040 (1976) (Courts as well as legislative bodies must afford equal protection).

Normally, in determining whether a class challenged as violating equal protection is rationally related to a legitimate state purpose this Court must answer: (1) whether the legislation has a legitimate purpose, and (2) whether it was

reasonable for the state's lawmakers to believe that use of the challenged class would promote that purpose. See *Western & Southern Life Ins. Co. v. State Bd of Equalization,* 451 US 648, 68 LEd 2d 514, 101 S Ct 207 (1981).

In this case, it is clear that the statutes (part of the New York Toxic Torts bill) were enacted for a legitimate purpose, to wit, to afford *all victims* injured as a result of direct or indirect exposure to harmful substances such as DES—which notoriously causes *latent* physical and property damage—a means of recovering their damages. The Toxic Torts legislation, on its face, is therefore constitutionally sound. See e.g. *New York ex rel Bryant v. Zimmerman,* 278 US 63, 73 LEd 184, 49 S Ct 61, 62, 785 (1928); see also *Hymowitz v. Eli Lilly v. Co.,* 73 NY2d 487, 541 NYS2d 941, cert den. ____US____, 110 S Ct 350 (1989).

The New York State Legislature did not limit the class entitled to recover to those making *direct* contact with the substance or to those in any particular generation. Indeed, in enacting section 2500-c of the Public Health Law, one legislator specifically recognized that the problems associated with DES were likely to grow over the years as exposed female off-spring reach reproductive age, one time when abnormalities become apparent. That such "abnormalities" could result in damage to the next generation of off-spring was thus implicitly acknowledged by the legislature as early as 1978, when the section of the Public Health Law was enacted.

But the *Court,* in applying the statute, created a separate subcategory of DES victims; those who were not directly exposed to the substance and those who, although suffering injuries one generation after those plaintiffs directly exposed to DES, nonetheless were physically damaged as a result of the drug's effects. In essence, the Court on its own revised or restricted permissible legislation, which it had no

constitutional right to do. See *in re Lawyers Westchester Mort & Title Co.*, 288 NY 40, 41 NE2d 449, cert den. 317 US 701, 87 LEd 560, 63 S Ct 527 (1942) (Courts may not revise or restrict legislation.); *Order of R. Telegraphers v. Chicago & NWR, Co.*, 362 US 330, 4 LEd 2d 774, 80 S Ct 781, reh. den. 362 US 984, 4 LEd 2d 1019, 80 S Ct 1056 (1962) (Courts may not create exceptions to a legislative plan.); *People v. Crane*, 214 NY 154, 108 NE 427, aff'd 39 US 195, 60 LEd 218, 36 S Ct 85 (1915) (Questions of policy are for determination by the legislature and not the courts.); *Matthews v. DeCastro*, 429 US 181, 50 LEd 2d 389, 97 S Ct 431 (1976) (Courts cannot properly be concerned with reasons that prompted legislature in creating classification.)

In applying a constitutional statute the court created a wholly *arbitrary* and thus unconstitutional classification, contrary to the explicit policy expressed by the Legislature in enacting the Toxic Torts bill. That policy was to afford a remedy to *all victims* of DES regardless of generational boundaries or of the particular mechanism through which the DES exposure caused the injuries.

Finally, by denying petitioner a cause of action afforded by the Legislature, the court impermissible deprived petitioner of his property rights to an existing cause of action. See *Sliosberg v. New York Life Ins., Co.*, 217 App. Div. 67, 216 NY Supp 215, aff'd 244 NY 482, 155 NE 749, cert den. 275 US 526, 72 LEd 407, 48 S Ct 19 and aff'd 244 NY 599, 155 NE 913 (1927).

CONCLUSION.

For the foregoing reasons, the petition for a writ of certiorari to the Court of Appeals of the State of New York should be granted.

Respectfully submitted,

NORMAN E. FROWLEY
Appellate Counsel for Petitioner
LAW OFFICES OF LEONARD L. FINZ, P.C.
Counsel of Record for Petitioner

APPENDIX A—Order of the New York State Court of Appeals Denying Motion for Leave to Appeal to the Court of Appeals.

COURT OF APPEALS

STATE OF NEW YORK.

At a session of the Court, held at Court of Appeals Hall in the City of Albany on the ninth day of May A. D. 1991

Present, HON. SOL WACHTLER, Chief Judge, presiding.

MO. NO. 373

KAREN ENRIGHT, an Infant &c., *et al.*,

Respondents,

v.

ELI LILLY & COMPANY, *et al.*,

Appellants.

A motion for reargument to the Court of Appeals in the above cause having been heretofore made upon the part of the respondents herein and papers having been submitted thereon and due deliberation thereupon had, it is

ORDERED, that the said motion be and the same hereby is denied.

Judge Bellacosa took no part.

STUART M. COHEN
Deputy Clerk of the Court

APPENDIX B—Opinion of the New York State Court of Appeals, February 19, 1991.

77 N.Y.2d 377

Karen ENRIGHT, an Infant, by Patricia ENRIGHT, Her Parent and Natural Guardian, et al., Respondents,

v.

ELI LILLY & COMPANY, et al., Appellants.

Court of Appeals of New York.

Feb. 19, 1991.

Child born with birth defects and her parents brought action to recover damages from manufacturers of diethylstilbestrol (DES). The Supreme Court, Chenango County, Ingraham, J., 141 Misc.2d 194, 533 N.Y.S.2d 224, granted manufacturers' motions for summary judgment dismissing all claims brought on behalf of child and dismissing certain causes of action of child's parents. On cross appeals, the Supreme Court, Appellate Division, 155 A.D.2d 64, 553 N.Y.S.2d 494, reinstated cause of action asserted on behalf of child sounding in strict products liability, and affirmed as so modified. Manufacturers appealed upon Appellate Division's grant of permission and certification of question as to whether it erred as matter of law by reversing so much of trial court order as granted manufacturers' motions dismissing strict products liability cause of action. The Court of

Appeals, Wachtler, C.J., held that strict products liability of manufacturers of DES would not extend to "third generation" plaintiff, whose injuries were allegedly caused by her premature birth, which in turn allegedly resulted from damage to her mother's reproductive system caused by mother's in utero exposure to DES.

Affirmed as modified; certified question answered affirmatively.

Hancock, J., filed opinion dissenting in part.

1. Limitation of Actions ⇐95(5)

Implicit in language of "discovery rule" for statute of limitations is notion that some contact with substance is essential to strict liability cause of action against manufacturer of substance. McKinney's CPLR 214–c, subds. 1, 2.

2. Statutes ⇐236

Even a remedial statute must be given meaning consistent with words chosen by legislature.

3. Statutes ⇐236

Role of courts is to give effect not only to remedy provided by remedial statute, but also words that delimit remedy.

4. Drugs and Narcotics ⇐18

Strict products liability of manufacturers of drug diethylstilbestrol (DES) would not extend to "third generation" plaintiff, whose injuries were allegedly caused by

her premature birth, which in turn allegedly resulted from damage to her mother's reproductive system caused by mother's in utero exposure to DES.

5. Drugs and Narcotics ⇐18

Strict products liability of manufacturers of drug diethylstilbestrol (DES) would be limited to those who ingested drug or were exposed to it in utero.

6. Drugs and Narcotics ⇐18

Public policy favoring availability of prescription drugs does not provide drug manufacturers with immunity from liability stemming from their failure to conduct adequate research and testing prior to marketing of their products.

7. Courts ⇐91(1)

Fact that rule provided by Court of Appeals case is based on policy grounds should not diminish its status as rule of law.

8. Torts ⇐20

Injury to mother which resulted in injuries to later-conceived child does not establish cause of action in favor of child against original tort-feasor.

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1380 Arthur H. Bryana, Priscilla Budeiri, Isabel Marcus and Lucinda M. Finley, Buffalo, for Trial Lawyers for Public Justice, amicus curiae.

OPINION OF THE COURT

WACHTLER, Chief Judge.

The question in this case is whether the liability of manufacturers of the drug diethylstilbestrol (DES) should extend to a so-called "third generation" plaintiff, the granddaughter of a woman who ingested the drug. According to the allegations of the complaint, the infant plaintiff's injuries were caused by her premature birth, which in turn resulted from damage to her mother's reproductive system caused by the mother's in utero exposure to DES. We hold, in accord with our decision in *Albala v. City of New York*, 54 N.Y.2d 269, 445 N.Y.S.2d 108, 429 N.E.2d 786, that in these circumstances no cause of action accrues in

favor of the infant plaintiff against the drug manufacturers.

I.

The plaintiffs in this case are Karen Enright, born August 9, 1981, and her parents, Patricia and Earl Enright. According to their complaint, the events underlying this action began more than 30 years ago, when Karen Enright's maternal grandmother ingested DES during a pregnancy which resulted in the birth of plaintiff Patricia Enright on January 29, 1960. Plaintiffs allege that because of her in utero exposure to DES, Patricia Enright developed a variety of abnormalities and deformities in her reproductive system. As a result, several of her pregnancies terminated in spontaneous abortions and another resulted in the premature birth of Karen Enright. Karen suffers from cerebral palsy and other disabilities that plaintiffs attribute to her premature birth and, ultimately, to her grandmother's ingestion of DES.

This action was commenced by Patricia and Earl Enright individually and on behalf of their daughter against several manufacturers of DES. After issue was joined, the defendants sought summary judgment dismissing the complaint. Defendants contended that the actions were barred by the Statute of Limitations and by plaintiffs' inability to identify the manufacturer of the drug ingested by Karen's grandmother.

In addition, defendants argued that Karen's claims of a preconception tort presented no cognizable cause of action.

Supreme Court, relying principally on *Albala v. City of New York*, 54 N.Y.2d 269, 445 N.Y.S.2d 108, 429 N.E.2d 786, *supra*, agreed with defendants that those claims stemming from Karen's injuries were not legally cognizable and dismissed all four causes of action brought on her behalf and those asserted by her parents for their emotional injuries resulting from Karen's birth. Defendants' motions were otherwise denied, however, leaving intact Patricia Enright's claims relating to her own physical injuries and Earl Enright's derivative claim based upon his wife's injuries.

On cross appeals, the Appellate Division modified by reinstating the third cause of action in the complaint—that cause of action brought on behalf of Karen Enright based upon strict products liability. The Appellate Division agreed with Supreme Court that *Albala* foreclosed preconception tort liability based upon negligence, but held that public policy in favor of providing a remedy for DES victims justified recognizing a strict products liability cause of action. 155 A.D.2d 64, 553 N.Y.S.2d 494.

Defendants sought leave to appeal to this Court, which the Appellate Division granted, certifying to us the question: "Did this court err, as a matter of law, by reversing so much of the Supreme Court order as granted defendants' motions dis-

missing[382] the third cause of action in the complaint and, as so modified, affirming the order?" That question must be answered in the affirmative.

We note that no issues are raised on this appeal regarding the still pending claims of Patricia and Earl Enright based on the injuries allegedly sustained by Patricia Enright due to her own in utero exposure to DES. Most of defendants' attacks on those claims were defused by our recent decision in *Hymowitz v. Lilly & Co.*, 73 N.Y.2d 487, 541 N.Y.S.2d 941, 539 N.E.2d 1069, *cert. denied* — U.S. ——, 110 S.Ct. 350, 107 L.Ed.2d 338. Nor do plaintiffs challenge the Appellate Division order to the extent that it affirmed the dismissal of those causes of action brought on behalf of Karen Enright sounding in negligence, breach of warranty and fraud.

Thus, the only issue before us is the propriety of the Appellate Division's reinstatement of the strict products liability cause of action on behalf of Karen Enright, this so-called "third generation" plaintiff.

II.

The tragic DES tale is well documented in this Court's decisions and need not be recounted here (*see, e.g., Hymowitz v. Lilly & Co., supra; Bichler v. Lilly & Co.*, 55 N.Y.2d 571, 450 N.Y.S.2d 776, 436 N.E.2d 182). It is sufficient to note that between 1947 and 1971, the drug, a synthetic estrogen-like substance produced by approximately 300 manufacturers, was prescribed

for use and ingested by millions of pregnant women to prevent miscarriages. In 1971, the Food and Drug Administration banned the drug's use for the treatment of problems of pregnancy after studies established a link between in utero exposure to DES and the occurrence in teen-age women of a rare form of vaginal and cervical cancer. Plaintiffs allege that in utero exposure to DES has since been linked to other genital tract aberrations in DES daughters, including malformations or immaturity of the uterus, cervical abnormalities, misshapen Fallopian tubes and abnormal cell and tissue growth, all of which has caused in this population a marked increase in the incidence of infertility, miscarriages, premature births and ectopic pregnancies.

The Legislature and this Court have both expressed concern for the victims of this tragedy by removing legal barriers to their tort recovery—barriers which may have had their place in other contexts, but which in DES litigation worked a peculiar injustice because of the ways in which DES was developed, marketed and sold and because of the insidious nature of its harm.

For example, prior to 1986, the longstanding rule in this State was that a cause of action for personal injuries caused by a toxic substance accrued and the limitations period began to run upon exposure to the substance (*see, Fleishman v. Lilly & Co.*, 62 N.Y.2d 888, 478 N.Y.S.2d 853, 467 N.E.2d 517, *cert. denied* 469 U.S. 1192, 105 S.Ct. 967, 83 L.Ed.2d 972). The Legisla-

ture, recognizing that under this rule claims for injuries caused by exposure to DES and other toxic substances were often time barred before the harmful effects of the exposure could be discovered, changed the law to provide that the limitations period in exposure cases begins to run upon discovery of the injury (*see*, CPLR 214-c; L.1986, ch. 682, § 2). At the same time, the Legislature revived for one year previously time-barred causes of action based on exposure to DES and four other toxic substances (L.1986, ch. 682, § 4).

More recently, this Court responded to the fact that—for a variety of reasons unique to the DES litigation context—a DES plaintiff generally finds it impossible to identify the manufacturer of the drug that caused her injuries. We held that liability could be imposed upon DES manufacturers in accordance with their share of the national DES market, notwithstanding the plaintiff's inability to identify the manufacturer particularly at fault for her injuries (*see, Hymowitz v. Lilly & Co., supra*).

III.

In the present case, we are asked to do something significantly different. We are asked, not to remove some barrier to recovery that presents unique problems in DES cases, but to recognize a cause of action not available in other contexts simply (or at least largely) because this is a DES case.

In *Albala v. City of New York*, 54 N.Y.2d 269, 271, 445 N.Y.S.2d 108, 429

N.E.2d 786, *supra*, we were presented with the question "whether a cause of action lies in favor of a child for injuries suffered as a result of a preconception tort committed against the mother". There, the mother suffered a perforated uterus during the course of an abortion. Four years later, she gave birth to a brain-damaged child, whose injuries were allegedly attributable to the defendants' negligence in perforating the mother's uterus. We declined, as a matter of policy, to recognize a cause of action on behalf of the child, believing that to do so would "require the extension of traditional tort concepts beyond manageable [384] bounds" (*id.*, at 271–272, 445 N.Y. S.2d 108, 429 N.E.2d 786). Among other things, we were concerned with "the staggering implications of any proposition which would honor claims assuming the breach of an identifiable duty for less than a perfect birth" and the difficulty, if such a cause of action were recognized, of confining liability by other than artificial and arbitrary boundaries (*id.*, at 273, 445 N.Y. S.2d 108, 429 N.E.2d 786, citing *Park v. Chessin*, 46 N.Y.2d 401, 413 N.Y.S.2d 895, 386 N.E.2d 807; *Howard v. Lecher*, 42 N.Y.2d 109, 397 N.Y.S.2d 363, 366 N.E.2d 64).

The case now before us differs from *Albala* only in that the mother's injuries in this case were caused by exposure to DES instead of by medical malpractice. A different rule is justified, therefore, only if

that distinction alters the policy balance we struck in *Albala*.

The primary thrust of plaintiffs' argument and the Appellate Division's decision is that DES itself alters that balance. From the Legislature's actions in modifying the applicable Statute of Limitations and reviving time-barred DES cases and from our adoption of a market-share liability theory in *Hymowitz*, plaintiffs perceive a public policy favoring a remedy for DES-caused injuries sufficient to overcome the countervailing policy considerations we identified in *Albala*. The implication, of course, is that the public interest in providing a remedy for those injured by DES is stronger than the public interest in providing a remedy for those injured by other means—medical malpractice, for example. We do not believe that such a preference has been established.

To be sure, recent developments demonstrate legislative and judicial solicitude for the victims of DES, but they do not establish DES plaintiffs as a favored class for whose benefit all traditional limitations on tort liability must give way. To the extent that special rules have been fashioned, they are a response to unique procedural barriers and problems of proof peculiar to DES litigation.

[1–3] For example, the Legislature's enactment of a "discovery" Statute of Limitations was directed at opening up traditional avenues of recovery by removing a proce-

dural barrier that was unreasonable given the nature of DES injuries. Nothing in the legislation suggests that the Legislature intended to expand the basis for liability. Indeed, the language of the statute suggests the opposite conclusion. The discovery rule applies in cases of injury caused by "the latent effects of exposure to any substance * * * upon or within the body" (CPLR 214–c[2]). Exposure is defined as "direct or indirect [385] exposure by absorption, contact, ingestion, inhalation or injection" (CPLR 214–c[1]). Implicit in this language is the notion that some contact with the substance is essential to a cause of action, an element lacking here.[1]

Similarly, our adoption of market-share liability was not prompted by some uncontrolled momentum favoring recovery by all DES plaintiffs; rather, it was justified because identification of the DES manufacturer was an insurmountable barrier in the "singular case [where] manufacturers

1. It is true enough, as the dissent points out, that CPLR 214–c is a remedial statute and such statutes should be "liberally construed to effectuate their aims" (dissenting opn., at 392, p. 558 of 568 N.Y.S.2d, p. 206 of 570 N.E.2d). But even a remedial statute must be given a meaning consistent with the words chosen by the Legislature—those words define the scope of the remedy that the Legislature deemed appropriate. In our view, the role of the courts is to give effect not only to the remedy, but also to the words that delimit the remedy. Under the dissenter's formulation, apparently, the courts are free to extend the remedy as far as they see fit; the statute merely provides a starting point and a direction.

act[ed] in a parallel manner to produce an identical, generically marketed product, which causes injury many years later" (*Hymowitz v. Lilly & Co., supra*, 73 N.Y.2d at 508, 541 N.Y.S.2d 941, 539 N.E.2d 1069). These unique features of DES cases not only made identification difficult, but also made it less relevant to culpability than in other products liability actions, since the tortious conduct of DES manufacturers pervaded the industry. Thus, the market-share theory was adopted "to apportion liability so as to correspond to the over-all culpability of each defendant, measured by the amount of risk of injury each defendant created to the public-at-large." (*Id.*, at 512, 541 N.Y.S.2d 941, 539 N.E.2d 1069.) The *Hymowitz* decision did not create a new cause of action; it simply adjusted the rules governing a traditional cause of action to circumvent what in this limited context were unreasonable obstacles.

[4] In the present case, however, neither plaintiffs, the Appellate Division, nor the dissent has identified any unique feature of DES litigation that justifies the novel proposition they advance—recognition of a multigenerational cause of action that we have refused to recognize in any other context. The fact that this is a DES case does not by itself justify a departure from the *Albala* rule.

Closer to the mark, though still falling short, is plaintiffs' second argument. They note that *Albala* was a negligence case and that we left open the question whether a

different result might obtain under a strict products liability theory [1386] because of the potentially different policy considerations in such a case (*see, Albala v. City of New York, supra,* 54 N.Y.2d at 274, n., 445 N.Y.S.2d 108, 429 N.E.2d 786). Having now examined the question in the context of this particular strict products liability claim, we find no basis for reaching a different conclusion than we did in *Albala.*

On one hand, weighing somewhat more heavily in favor of recovery in a strict products liability action than in ordinary negligence actions is the policy of diverting the burden of product-caused injuries from the innocent victim to the manufacturer. The product manufacturer is generally in a better position than an individual tort-feasor to distribute this burden by passing the costs along to customers in the cost of the product. This is one justification offered for holding manufacturers of defective products strictly liable for injury caused by their products without regard to privity, foreseeability or due care (*see, Codling v. Paglia,* 32 N.Y.2d 330, 341, 345 N.Y.S.2d 461, 298 N.E.2d 622; Prosser and Keeton, Torts, at 692–693 [5th ed.]).

Of course, imposing liability on the manufacturer in such circumstances also serves to encourage the development of safer products (*Codling v. Paglia, supra,* at 341, 345 N.Y.S.2d 461, 298 N.E.2d 622; *Sukljian v. Ross & Son Co.,* 69 N.Y.2d 89, 95, 511 N.Y.S.2d 821, 503 N.E.2d 1358), but this rationale is not a distinctive feature of

strict products liability theory, since imposition of liability on a negligent tort-feasor is also based in part on a policy of deterrence (*see, McDougald v. Garber*, 73 N.Y.2d 246, 254, 538 N.Y.S.2d 937, 536 N.E.2d 372). This factor, therefore, does not appear to add anything new to the mix of policy considerations that was not also present in *Albala*. We recognize, however, that a widely distributed product, if defective, presents a risk to a broad range of potential victims. For that reason, although the need for deterrence is not unique to the products liability context, it may have added weight there.

[5] Despite these considerations, the countervailing ones remain strong enough to preclude us from recognizing a cause of action here. To begin, the concerns we identified in *Albala* are present in equal measure here. The nature of the plaintiffs' injuries in both cases—birth defects—and their cause—harm to the mothers' reproductive systems before the children were conceived—are indistinguishable for these purposes. They raise the same vexing questions with the same "staggering implications" (*Albala v. City of New York*, *supra*, 54 N.Y.2d at 273, 445 N.Y.S.2d 108, 429 N.E.2d 786).[2] As [387] in *Albala*, the

2. This—not fear of defensive medicine—was what we identified in *Albala* as "the central concern" that led to the policy choice we made in that case (*see*, 54 N.Y.2d, at 273, 445 N.Y.S.2d 108, 429 N.E.2d 786). The dissent fails to explain why this same concern is not equally

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cause of action plaintiffs ask us to recognize here could not be confined without the drawing of artificial and arbitrary boundaries. For all we know, the rippling effects of DES exposure may extend for generations. It is our duty to confine liability within manageable limits (*see, Tobin v. Grossman*, 24 N.Y.2d 609, 619, 301 N.Y.S.2d 554, 249 N.E.2d 419; Prosser, *Palsgraf Revisited*, 52 Mich.L.Rev. 1, 27). Limiting liability to those who ingested the drug or were exposed to it in utero serves this purpose.

At the same time, limiting liability in this fashion does not unduly impair the deterrent purposes of tort liability. The manufacturers remain amenable to suit by all those injured by exposure to their product, a class whose size is commensurate with the risk created. In addition, we note that the tort system is not the only means of encouraging prescription drug safety; the Federal Food and Drug Administration has primary responsibility for that task (*see*, Note, *A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals*, 103 Harv.L.Rev. 773). We do

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(Footnote continued.)

implicated here, and thus fails to provide any basis for distinguishing *Albala* beyond the observation that DES cases are "special" (dissenting opn., at 391, n. 1, p. 558 of 568 N.Y.S.2d, p. 206 of 570 N.E.2d). While we agree that DES cases have unique features, the question is not simply whether DES cases are special, but whether they are different in some way that justifies a departure from the established rule that applies to other cases.

not suggest, as some have *(see, id.)*, that for this reason the judicial system should abandon its traditional role. But in light of the FDA's responsibility in this area, the need for the tort system to promote prescription drug safety is at least diminished.

That the product involved here is a prescription drug raises other considerations as well. First, as in most prescription drug cases (*see*, Vinson & Slaughter, Products Liability: Pharmaceutical Drug Cases, at 123–140), liability here is predicated on a failure to warn of dangers of which the manufacturers knew or with adequate testing should have known. Such a claim, though it may be couched in terms of strict liability, is indistinguishable from a negligence claim (*see, Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 423 N.Y.S.2d 95, *aff'd on opn. below* 52 N.Y.2d 768, 436 N.Y.S.2d 614, 417 N.E.2d 1002). Concepts of reasonable care and foreseeability are not divorced from this theory of liability, as they may be under other strict products liability predicates. Thus, the effort to distinguish this case from *Albala* is strained.

[6] More important, however, is recognition that public policy favors the availability of prescription drugs even though most carry some risks (*see, Brown v. Superior Ct.*, 44 Cal.3d 1049, 245 Cal.Rptr. 412, 751 P.2d 470, 478–479; Restatement [Second] of Torts § 402A, comment *k;* Vinson & Slaughter, *op. cit.*, at 123–126). That is not to say that drug manufacturers

should enjoy immunity from liability stemming from their failure to conduct adequate research and testing prior to the marketing of their products. They do not enjoy such immunity, as evidenced by our recognition of liability in favor of those who have been injured by ingestion or in utero exposure to DES. But we are aware of the dangers of overdeterrence—the possibility that research will be discouraged or beneficial drugs withheld from the market. These dangers are magnified in this context, where we are asked to recognize a legal duty toward generations not yet conceived.

The dissent would have us believe that this case involves nothing but application of straightforward strict products liability doctrine. But this case is fundamentally different in the same way that *Albala* was fundamentally different from other negligence cases. In neither this case nor *Albala* was the infant plaintiff exposed to the defendants' dangerous product or negligent conduct; rather, both were injured as a consequence of injuries to the reproductive systems of their mothers.

We agree with the dissenter that " 'like cases should be treated alike.' " (Dissenting opn., at 397, p. 561 of 568 N.Y.S.2d, p. 209 of 570 N.E.2d.) This is not only a fundamental principle of justice, it is also the underpinning of the doctrine of stare decisis. It is, indeed, precisely why we are bound to apply the rule of *Albala* here, in

the absence of some difference between the two cases upon which a principled distinction can be drawn.

[7] The dissent, however, discounts the precedential value of *Albala* because it was based on *"policy grounds"* and therefore—in the dissenter's view—"poses no *legal bar* to recovery" (dissenting opn., at 394, p. 560 of 568 N.Y.S.2d, p. 208 of 570 N.E.2d). That the *Albala* rule is based on policy grounds, however, should not diminish its status as a rule of law. All legal rules, including those the dissent relies upon, are policy-based.

By adhering to *Albala*, therefore, our decision today follows established law. The dissenter, on the other hand, would expand liability beyond traditional bounds in the face of precedent from this court to the contrary, and accuses the majority of usurping the legislative function by failing to do so (dissenting opn., at 397, p. 561 of 568 N.Y.S.2d, p. 209 of 570 N.E.2d). It strikes us as a unique view of the judicial role that would allow the court to expand liability at [389] will, but require legislative action before adhering to established limits.

[8] In sum, the distinctions between this case and *Albala* provide no basis for a departure from the rule that an injury to a mother which results in injuries to a later-conceived child does not establish a cause of action in favor of the child against the original tort-feasor. For this reason, we

decline to recognize a cause of action on behalf of plaintiff Karen Enright.

Accordingly, the order of the Appellate Division should be modified, with costs to defendants, by granting defendants' motions for summary judgment dismissing the third cause of action and, as so modified, affirmed. The certified question should be answered in the affirmative.

HANCOCK, Judge (dissenting).

Karen Enright is one of a class of thousands of persons who have allegedly suffered devastating abnormalities and injuries resulting from defendants' marketing of DES. Is there any basis in the law or social policy or any principled reason in justice and fairness for holding that she—unlike other members of the class—should not be permitted to prove her case? I am convinced there is no such basis or reason. Today, however, in what appears to mark an abrupt change in the course of New York strict products liability jurisprudence, a cut-back on recent precedent and a rejection of policy established by the Legislature and accepted by our Court, the majority denies her the right to sue.

Under settled strict products doctrine (*see, e.g., Codling v. Paglia*, 32 N.Y.2d 330, 338–342, 345 N.Y.S.2d 461, 298 N.E.2d 622; Prosser and Keeton, Torts § 98 [5th ed.]) and *Hymowitz v. Lilly & Co.*, 73 N.Y.2d 487, 541 N.Y.S.2d 941, 539 N.E.2d 1069, *cert. denied* — U.S. ——, 110 S.Ct. 350,

107 L.Ed.2d 338, there can now be no question that persons in the position of Karen Enright's mother would have a right to recover for injuries to their reproductive systems. Yet, the majority holds that Karen Enright has no right to recover, solely because she was not conceived at the time that her mother was exposed to DES in utero. But the majority gives no satisfactory reason why this fact justifies the decision to exclude her from the class of those permitted to recover for injuries caused by DES. For reasons which follow I cannot accept this result and vote to affirm the order of the Appellate Division holding that Karen Enright states a valid cause of action in strict products liability.

[390]

Preliminarily, I note that the question of whether there can be a recovery in a products liability case for a preconception injury is before us in a dismissal motion under CPLR 3211(a)(7). Thus, the case presents no legal hurdles with respect to foreseeability or causation. Clearly it cannot be said as a matter of law—assuming it was foreseeable that Karen's mother's uterus might be deformed from the DES—that it was not also foreseeable that Karen Enright would be born prematurely because of this deformity and afflicted with cerebral palsy and the other appalling consequences from which she suffers. Nor is the possibility of additional difficulties in establishing causation at trial a reason for dismissal (*see,*

Woods v. Lancet, 303 N.Y. 349, 356, 102 N.E.2d 691; Prosser and Keeton, *op. cit.*, § 55, at 368; Comment, *Preconception Torts: Foreseeing the Unconceived*, 48 U.Colo.L.Rev. 621, 625–627). The complaint alleges that plaintiff's injuries were foreseeable and that they were caused by her mother's exposure to DES. In deciding whether plaintiff has stated a cause of action on this motion we must assume these allegations to be true (*see, Becker v. Schwartz*, 46 N.Y.2d 401, 408, 413 N.Y.S.2d 895, 386 N.E.2d 807). In any event the majority does not ground its decision on these or other propositions of tort law, but rather on what it perceives to be policy reasons which dictate that Karen Enright's claim should be dismissed.

The matrix of social policy and legal precedent on which Karen Enright founds her claim has been constructed by the Legislature and our Court. In 1986, the Legislature passed the Governor's Program Toxic Torts bill and adopted a "discovery" Statute of Limitations (CPLR 214–c) for the express purpose of remedying the injustice of denying any right to relief to persons suffering from the latent effects of injuries from DES and other substances (L.1986, ch. 682). In signing the Toxic Torts bill into law, the Governor noted that "this measure * * * remedies a fundamental injustice in the laws of our State which has deprived persons suffering from exposure

to toxic or harmful substances from having an opportunity to present their case in court[,]" that "[t]his measure remedies the injustices suffered by all of the currently known categories of victims of exposure * * * includ[ing] persons who have suffered serious injuries as a result of exposure to diethylstilbestrol (DES)" and that "this legislation culminates a multi-year effort by these victims to achieve this long overdue reform in our law. It is a victory for justice, and an example [391] of democracy in action" (Governor's Mem. of approval, 1986 McKinney's Session Laws of N.Y., at 3182–3184).

In *Hymowitz v. Lilly & Co.*, 73 N.Y.2d 487, 541 N.Y.S.2d 941, 539 N.E.2d 1069, *supra*, this Court recognized the unique characteristics of DES [1] and gave practical

1. The Court in *Hymowitz* in devising its national market-share formulation emphasized that its action was prompted by the unusual nature of the problems caused by DES, in these words:

"We stress, however, *that the DES situation is a singular case*, with manufacturers acting in a parallel manner to produce an identical, generically marketed product, which causes injury many years later, *and which has evoked a legislative response reviving previously barred actions. Given this unusual scenario*, it is more appropriate that the loss be borne by those that produced the drug for use during pregnancy, rather than by those who were injured by the use, even where the precise manufacturer of the drug cannot be identified in a particular action." (73 N.Y.2d 487, 508, 541 N.Y.S.2d 941, 539 N.E.2d 1069 [emphasis added].)

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effect to the intent of the Legislature's important and much-heralded reform. In a precedent which created a means for a victim of DES to recover notwithstanding her inability to identify the manufacturer, the *Hymowitz* Court stressed that the "insidious nature" of DES injuries, the expectations created by the Legislature and the "dictates of justice and fairness" justified the remedy. The Court wrote:

> "Indeed, it would be inconsistent with the reasonable expectations of a modern society to say to these plaintiffs that because of *the insidious nature of an injury that long remains dormant*, and because so many manufacturers, each behind a curtain, contributed to the devastation, the cost of injury should be borne by the innocent and not the wrongdoers. *This is particularly so where the Legislature consciously created these expectations by reviving hundreds of DES cases. Consequently, the ever-evolving dictates of justice and fairness, which are the heart of our common-law system, require formation of a*

(Footnote continued.)

The majority suggests (majority opn., at 385, p. 554 of 568 N.Y.S.2d, p. 202 of 570 N.E.2d) that DES strict products cases are not special and should be treated no differently from other tort cases such as malpractice. Such suggestion is clearly at odds with the above-quoted passage from *Hymowitz* and with the record of special concern for DES victims shown by the Legislature (*see, e.g.*, Governor's Mem. of approval, July 30, 1986, 1986 McKinney's Session Laws of N.Y., at 3182) and by our Court in *Hymowitz*

remedy for injuries caused by DES (*see, Woods v. Lancet*, 303 N.Y. 349, 355, 102 N.E.2d 691; *see, also*, [392]Kaye, *The Human Dimension in Appellate Judging: A Brief Reflection on a Timeless Concern*, 73 Cornell LRev 1004)." (*Id.*, 73 N.Y.2d at 507, 541 N.Y.S.2d 941, 539 N.E.2d 1069 [emphasis added].)

The majority, nonetheless, gives CPLR 214–c a narrow reading as support for its refusal to recognize Karen Enright's claim, suggesting that "[i]mplicit in [its] language is the notion that some contact with the substance is essential" (majority opn., at 385, p. 554 of 568 N.Y.S.2d, p. 202 of 570 N.E.2d). Nothing in the statute's legislative history nor in its wording leads to this construction. Indeed, "exposure" under the statute "means direct or *indirect* exposure by absorption, contact, ingestion, inhalation or injection" (CPLR 214–c[1] [emphasis added]). As the Commentary notes, the new discovery rule applies "when the plaintiff has been the victim of exposure to a toxic substance, *the critical term 'exposure' is broadly defined*" (McLaughlin, Practice Commentaries, McKinney's Cons. Laws of N.Y., Book 7B, CPLR C214–c:1, at 631 [emphasis added]). Given the broad language in the statute and the legislative history, the majority's unduly constricted reading of the statute is inconsistent with the fundamental notion that remedial statutes are to be liberally construed to effectuate their aims and to promote justice (*see,*

McKinney's Cons.Laws of N.Y., Book 1, Statutes § 321).

In *Codling v. Paglia*, 32 N.Y.2d 330, 345 N.Y.S.2d 461, 298 N.E.2d 622, *supra*, the seminal case in which we adopted strict products liability in this State, we summarized the reasons in social policy, in the economic realities of mass production and distribution and in the considerations of "justice and common sense" for the rule that manufacturers which place defective products in the stream of commerce should bear the financial burdens of their harmful consequences—rather than the innocent persons who suffer the harm (*id.*, at 340–342, 345 N.Y.S.2d 461, 298 N.E.2d 622; Restatement [Second] of Torts § 402A, comment *c*). These general policies underlying strict products liability as well as the special policies pertaining to DES recognized by the Legislature in adopting CPLR 214–c and implemented by our Court in *Hymowitz* apply *no less* to Karen Enright's claim than to the claims of other DES victims. What, then, are the policy reasons seen by the majority as compelling today's decision? There appear to be three. None is availing.

First, the majority cites defendants' arguments concerning the "staggering implications" and "rippling effects" (majority opn., at 386, 387, pp. 554, 555 of 568 N.Y.S.2d, pp. 202, 203 of 570 N.E.2d) that a decision upholding Karen Enright's claim might have. But this sort of "floodgates of litigation" alarum seems singular-

ly unpersuasive in view of our Court's repeated admonitions that it is not "a ground for denying a cause of action that there will be a proliferation of claims" and *"if a cognizable wrong has been committed that there must be a remedy, whatever the burden of the courts."* (*Tobin v. Grossman*, 24 N.Y.2d 609, 615, 301 N.Y. S.2d 554, 249 N.E.2d 419 [emphasis added]; *see, Bovsun v. Sanperi*, 61 N.Y.2d 219, 231, 473 N.Y.S.2d 357, 461 N.E.2d 843; *Battalla v. State of New York*, 10 N.Y.2d 237, 240–242, 219 N.Y.S.2d 34, 176 N.E.2d 729.) Beyond that, however, when defendants' arguments are applied here to urge that although claims of DES daughters should be allowed the claims of granddaughters should not be, their forebodings strike a peculiarly ironic note: i.e., the very fact of the "insidious nature" of DES which may make the defendants liable for injuries to a future generation is advanced as the reason why they should not be liable for injuries to that generation. Should we be saying to these defendants and other companies which manufacture drugs "you must be careful to produce reasonably 'safe' drugs and to warn of the risks of taking such drugs but in deciding whether a drug is 'safe' you may completely ignore the havoc a particular drug may wreck on a future generation?" I think not.

Second, the majority suggests that permitting a cause of action for Karen Enright could result in "overdeterrence—the possibility that research will be discouraged or beneficial drugs withheld from the mar-

ket." (Majority opn., at 388, p. 556 of 568 N.Y.S.2d, p. 204 of 570 N.E.2d.) But in deciding whether a particular claim for injuries from DES should be sustained, the deterrence factor is inconsequential. The wrongful conduct of the drug companies in producing and marketing DES and similarly harmful products for use by pregnant women stopped more than a generation ago when the enormity of the damage from DES became known. The sole question now involves the remedy for this past wrong, not deterrence: i.e., whether the remedy for DES victims made possible by the Legislature in CPLR 214–c and given effect by our Court in *Hymowitz* should be withheld from a granddaughter who suffers injuries from this wrong. But even if deterrence is assumed to be a relevant issue, should we be any less concerned with deterring the development of unsafe drugs which may cause latent damage to the third generation than to the second? Again, I think not.

Finally, in what has the ring of an economic cost-benefit analysis, the majority suggests that its generational line-drawing is proper because the manufacturers' exposure to liability [394] is "commensurate with the risk created." (Majority opn., at 387, p. 555 of 568 N.Y.S.2d, p. 203 of 570 N.E. 2d.) The argument is seen at once to be at odds with the rule that on this motion to dismiss Karen Enright's complaint (CPLR 3211[a][7]) the court must accept as true her allegations that she is a member of the

class of persons to whom the risk of injury was foreseeable (*see, Becker v. Schwartz, supra*, 46 N.Y.2d at 408, 413 N.Y.S.2d 895, 386 N.E.2d 807). But, in any event, the statement that liability should stop at Karen's mother's generation because it "is commensurate with the risk" is not a statement of an argument or of a legal or policy reason for a particular result. Rather, it is simply a statement of the Court's own policy determination as to where the risk—and, hence, the liability—stops. If, as the majority apparently believes, there are economic and social considerations which require that there be some arbitrary cutoff point in cases of this kind, such a statute of repose could easily be engrafted on the Toxic Torts legislation which revived the long-outlawed dormant injury claims for DES and other substances (*see*, CPLR 214–c; *see generally*, Comment, *Preconception Torts: Foreseeing the Unconceived*, 48 U.Colo.L.Rev. 621; Phillips, *An Analysis of Proposed Reform of Products Liability Statutes of Limitations*, 56 N.C.L.Rev. 663; Note, *Statutes of Limitations and the Discovery Rule in Latent Injury Claims: An Exception or the Law?*, 43 U.Pitt.L.Rev. 501, 520–523). Suffice it to say, our Legislature has not chosen to cut off the claims of injured persons in Karen Enright's generation.

II

As the primary support for its decision, the majority refers to *Albala v. City of*

New York, 54 N.Y.2d 269, 445 N.Y.S.2d 108, 429 N.E.2d 786, a negligence case involving a single act of medical malpractice. One point must be emphasized. The decision in *Albala* poses no *legal bar* to recovery for a preconception tort and the case cannot be cited for that purpose. The *Albala* Court denied recovery for a preconception tort under the circumstances in that case *solely on policy grounds*, not for any legal or metaphysical reason arising from the fact that the injury occurred before the plaintiff was conceived. Indeed, the *Albala* opinion leaves little doubt that, in a proper case, there would be no legal impediment to a cause of action based on a preconception injury.[2] In distinguishing *Jorgensen v. Meade Johnson Labs.*, 1[395]483 F.2d 237 [10th Cir.1973] the Court in *Albala* highlighted the significant difference between a malpractice case and one "for which there is strict liability without fault." (*Id.*, 54 N.Y.2d at 274, n., 445 N.Y.S.2d 108, 429 N.E.2d 786). The Court explained:

> "Under a products liability theory, once a defect in manufacture or design is established or there has been a failure to give adequate notice of foreseeable potential hazards, the liability of the manu-

2. To be sure, as the majority points out (majority opn., at 388, p. 556 of 568 N.Y.S.2d, p. 204 of 570 N.E.2d), both this case and *Albala* are "different from other negligence cases" in that in both the plaintiffs "were injured as a consequence of injuries to the reproductive systems of their mothers." But this difference is of no consequence (*see, infra*, at 394–396, pp. 560–572 of 568 N.Y.S.2d, pp. 208–20 of 570 N.E.2d).

facturer is extended to the entire class of persons thereby affected regardless of privity, foreseeability or due care (*Codling v Paglia*, 32 NY2d 330 [345 N.Y. S.2d 461, 298 N.E.2d 622]). *Accordingly, the necessity of establishing manageable bounds for liability is conspicuously absent. Since Jorgensen was not therefore concerned with the policy issues presented in the instant appeal, any reliance thereon is misplaced* (see, also, Robertson, Toward Rational Boundaries of Tort Liability for Injury to the Unborn: Prenatal Injuries, Preconception Injuries and Wrongful Life, 1978 Duke LJ 1401, 1436, 1438)." (*Id.*, 54 N.Y.2d at 274, n., 445 N.Y.S.2d 108, 429 N.E.2d 786 [emphasis added].)

Thus, as the *Albala* opinion makes clear (*id.*, at 274, n., 445 N.Y.S.2d 108, 429 N.E.2d 786), the single act of malpractice in that case did not involve the compelling social and economic policies which prompted our adoption of strict products liability (*see, e.g., Codling v. Paglia, supra*, 32 N.Y.2d at 338–342, 345 N.Y.S.2d 461, 298 N.E.2d 622; Prosser and Keeton, *op. cit.*, § 98; *supra*, at 392, p. 558 of 568 N.Y. S.2d, p. 206 of 570 N.E.2d). More importantly, *Albala* implicated none of the deeply felt special concerns for the victims of the widespread marketing of DES which influenced the enactment of CPLR 214–c (*see*, Governor's Mem. of approval, *op. cit.*, at 3182–3184; *Besser v. Squibb & Sons*, 146 A.D.2d 107, 114, 539 N.Y.S.2d 734).

In addition to what would seem to be the decisive policy differences between a malpractice action and a strict products liability action based on toxic tort, there is one significant factor impelling the Court's decision in *Albala* that has no bearing here—"the undesirable impact of encouraging the practice of 'defensive medicine'." (*Albala v. City of New York*, 54 N.Y.2d 269, 274, 445 N.Y.S.2d 108, 429 N.E.2d 786, *supra*.) The action in *Albala* was for the consequences of an improperly performed abortion. In denying recovery for injuries to a subsequently conceived child, the Court stressed:

[396] "A physician faced with the alternative of saving a patient's life by administering a treatment involving the possibility of adverse consequences to later conceived offspring of that patient would, if exposed to liability of the magnitude considered in this case, undoubtedly be inclined to advise against the treatment rather than risk the possibility of having to recompense a child born with a handicap. *Accordingly, society as a whole would bear the cost of our placing physicians in a direct conflict between their moral duty to patients and the proposed legal duty to those hypothetical future generations outside the immediate zone of danger.*" (*Id.*, at 274, 445 N.Y.S.2d 108, 429 N.E.2d 786 [emphasis added].)

Karen Enright's case, of course, does not involve the doctor-patient relationship and

does not concern questions pertaining to the standard of knowledge, ability and care required of physicians. No "undesirable impact" of encouraging defensive medicine can result from a case of strict products liability based on the marketing of an unsafe drug where—as the *Albala* Court, itself, noted—"once * * * there has been a failure to give adequate notice of foreseeable potential hazards, the liability of the manufacturer is extended to the *entire class of persons thereby affected* regardless of privity, foreseeability or due care (*Codling v Paglia*, 32 NY2d 330 [345 N.Y. S.2d 461, 298 N.E.2d 622])." (*Albala v. City of New York, supra*, 54 N.Y.2d at 274, n., 445 N.Y.S.2d 108, 429 N.E.2d 786 [emphasis added].)

Moreover, this case presents none of the difficult moral dilemmas or problems of medical ethics (referred to in *Albala*) which can confront a physician called upon to render medical treatment to a mother which may possibly impair her offspring. The sole question here is whether Karen Enright, an innocent member of the class of persons adversely affected by DES, should be permitted to recover. None of the policy considerations in *Albala* suggests that she should not be.

III

I am convinced that existing legal doctrine and established policy point unequivocally to a decision upholding Karen Enright's cause of action. Let us assume for

the sake of argument, however, that this is not so and that the appeal presents a "hard case" where there are no clearly discernible legal or policy guidelines. On this assumption, is there any underlying principled reason in fairness, justice or moral doctrine why Karen Enright's claim should be turned away? [397] (*See*, Dworkin, Taking Rights Seriously, ch. 4, "Hard Cases", at 81–130 [1978]; Murphy and Coleman, Philosophy of Law, at 52–59 [1984].) No such reason can be advanced because none exists. There are two fundamental principles of justice, however, which dictate that Karen Enright *should be* permitted to prove her case.

First, Karen Enright is a victim of what—if the allegations of her complaint are proven—amounts to a wrong of enormous proportions which inflicted grievous injuries on her and countless other innocent persons. Unless her case is barred on some legal or policy ground, she should be justly compensated for her injuries to the extent that our judicial system can accomplish this. Second, she is damaged no less than other victims of DES who make up the class. If they are permitted to recover, so should she be. To say that Karen Enright cannot recover is to abrogate one of the most basic of all principles—that "like cases should be treated alike".

Our established strict products liability jurisprudence mandated by considerations of "justice and common sense" (*see, e.g.*,

Hymowitz v. Lilly & Co., supra; Codling v. Paglia, supra), the compelling social policies prompting the adoption of the Toxic Torts bill (CPLR 214–c), decisions in other jurisdictions allowing recovery for preconception torts and the legal commentary *all* call for a decision permitting Karen Enright to prove her claim (*see, Jorgensen v. Meade Johnson Labs.*, 483 F.2d 237, *supra; Renslow v. Mennonite Hosp.*, 67 Ill.2d 348, 10 Ill.Dec. 484, 367 N.E.2d 1250; Prosser and Keeton, *op. cit.*, § 55, at 367–370; Robertson, *Toward Rational Boundaries of Tort Liability for Injury to the Unborn: Prenatal Injuries, Preconception Injuries and Wrongful Life*, 1978 Duke L.J. 1401, 1435–1439; Collins, *An Overview and Analysis: Prenatal Torts, Preconception Torts, Wrongful Life, Wrongful Death and Wrongful Birth: Time for a New Framework*, 22 J.Fam.L. 677; Comment, *Preconception Torts: Foreseeing the Unconceived*, 48 U.Colo.L.Rev. 621). Yet the majority denies her this right. This decision, I submit, amounts to an exercise in discretion and line-drawing reflecting social and economic policy choices which should be made not by Judges but by legislators. I dissent.

SIMONS, KAYE, ALEXANDER and TITONE, JJ., concur with WACHTLER, C.J.

HANCOCK, J., dissents in part and votes to affirm in a separate opinion.

BELLACOSA, J., taking no part.

Order modified, etc.

APPENDIX C—Opinion of the New York Supreme Court, Appellate Division, Third Department, March 22, 1990.

155 A.D.2d 64

Karen ENRIGHT, an Infant, by Patricia ENRIGHT, Her Parent and Natural Guardian, et al., Appellants–Respondents,

v.

ELI LILLY & COMPANY et al., Respondents–Appellants,

and

Abbott Laboratories et al., Respondents.

Supreme Court, Appellate Division, Third Department.

March 22, 1990.

Child born with birth defects and her parents brought action to recover damages from manufacturers of diethylstilbestrol (DES). The Supreme Court, Chenango County, Ingraham, J., 141 Misc.2d 194, 533 N.Y.S.2d 224, granted defendants' motions for summary judgment dismissing all claims brought on behalf of child and dismissing certain causes of action of child's parents. On cross appeals, the Supreme Court, Appellate Division, Casey, J.P., held that child had cause of action in strict products liability for injuries caused by her mother's exposure to diethylstilbestrol (DES) prior to child's conception.

Affirmed as modified.

Weiss, J., dissented with opinion.

1. Appeal and Error ⇐1078(1)

In light of appellant's failure to brief question of whether parents could recover damages for emotional distress resulting from birth of impaired child, appellants appeal from dismissal of that cause of action would be deemed abandoned.

2. Drugs and Narcotics ⇐18

Child born with birth defects had cause of action against manufacturers in strict products liability for injuries caused by her mother's exposure to diethylstilbestrol (DES) prior to child's conception; child's disabilities were allegedly caused by abnormalities and deformities in mother's reproductive system which, in turn, resulted from mother's in utero exposure to DES.

Law Offices of Leonard L. Finz, P.C. (Leonard L. Finz, of counsel), New York City and Di Joseph & Gluck (Steven Di Joseph, of counsel), New York City, for appellants-respondents.

Brown & Wood (Russel H. Beatie, Jr., Kenneth J. King and Charna L. Gerstenhaber, of counsel), New York City, for Eli Lilly & Co., respondent-appellant.

Phillips, Lytle, Hitchcock, Blaine & Huber (Alexander C. Cordes, of counsel), Buffalo, for E.R. Squibb & Sons, Inc. and others, respondents-appellants.

Before CASEY, J.P., and WEISS, MIKOLL, YESAWICH and HARVEY, JJ.

CASEY, Justice Presiding.

At issue on this appeal is whether the infant plaintiff, Karen Enright (hereinafter plaintiff), who was born with various physical disabilities, has a cause of action against the manufacturers of the drug diethylstilbestrol (hereinafter DES), which was allegedly ingested by plaintiff's grandmother while pregnant with plaintiff's mother and allegedly caused certain physical abnormalities in the mother which, in turn, caused the physical disabilities with which plaintiff was subsequently born. Supreme Court answered this question in the negative and dismissed all causes of action seeking to recover damages for plaintiff's injuries (141 Misc.2d 194, 533 N.Y.S.2d 224). We reach a contrary conclusion as to plaintiff's strict products liability cause of action.

The complaint alleges that plaintiff Patricia Enright (hereinafter Enright), who was born in 1960, was exposed to DES in utero as a fetus due to her mother's ingestion of DES during pregnancy at the direction of a physician. It is further alleged that due to this exposure Enright developed certain anatomical abnormalities and deformities in her reproductive system which subsequently prevented her from carrying a baby to full term. Enright gave birth to plaintiff in August 1981. It is alleged that plaintiff was born prematurely due to Enright's abnormalities developed as a result of exposure to DES and that plaintiff's premature birth caused plaintiff to develop severe dis-

abilities which will affect her for her entire life.

Enright and her husband commenced this action individually and on behalf of plaintiff against various manufacturers of DES, alleging causes of action sounding in negligence, strict products liability, breach of warranty and fraud. Damages are sought for physical and emotional injuries sustained by Enright, and physical injuries, pain and suffering sustained by plaintiff. Enright's husband asserts a derivative cause of action and a cause of action based upon the inability to have a healthy natural child of the marriage. The complaint also alleges that if it cannot be proven which of defendants manufactured the DES ingested by plaintiff's grandmother, recovery would be sought on the basis of alternative liability and/or enterprise liability and/or market share liability. After issue was joined, defendants moved for summary judgment, claiming, *inter alia*, that since New York does not recognize preconception tort liability, all claims based upon plaintiff's injuries must be dismissed; that no recovery could be had by parents for damages based upon emotional distress resulting from the birth of an impaired child; that the failure to identify the manufacturer of the DES ingested by plaintiff's grandmother required dismissal of all claims; and that Enright's claims were time barred since the revival statute under which they were brought (L.1986, ch. 682, § 4) is unconstitutional. Supreme Court held that

New York does not recognize preconception tort liability; that New York does not permit parents to recover for emotional distress resulting from the birth of an impaired child; that Enright and her husband could proceed on a concerted action theory of liability; and that the revival statute is constitutional. The resulting order generated the parties' cross appeals.

[1, 2] In the Court of Appeals' recent decision in *Hymowitz v. Lilly & Co.*, 73 N.Y.2d 487, 541 N.Y.S.2d 941, 539 N.E.2d 1069, *cert denied* — U.S. ——, 110 S.Ct. 350, 107 L.Ed.2d 338, which will govern the future course of this action, the court approved the use of a market share theory of liability in DES cases and upheld the constitutionality of the toxic tort revival provision. Thus, the only disputed issue to be resolved on this appeal concerns preconception tort liability.[1] Any analysis of this issue must begin with *Albala v. City of New York*, 54 N.Y.2d 269, 445 N.Y.S.2d 108, 429 N.E.2d 786, where the Court of Appeals held that a child does not have a cause of action against the doctors who negligently perforated the mother's uterus

1. Since plaintiffs have not briefed the question of whether parents may recover damages for emotional distress resulting from the birth of an impaired child, we deem plaintiffs' appeal from the dismissal of that cause of action to be abandoned. We reach a similar conclusion with respect to the dismissal of plaintiff Earl Enright's cause of action seeking damages based upon the inability to have a natural healthy child of the marriage.

some four years prior to conception, resulting in brain damage to the child during gestation.

The holding in *Albala* is based upon policy considerations, with the court expressing its "opinion that the recognition of a cause of action under these circumstances would require the extension of traditional tort concepts beyond manageable bounds" (*id.*, at 271–272, 445 N.Y.S.2d 108, 429 N.E.2d 786). Responding to the argument that the infant plaintiff's injuries were a foreseeable consequence of the defendants' malpractice, the *Albala* court said, "We determined long ago in a case involving policy issues as sensitive as the ones at bar that foreseeability alone is not the hallmark of legal duty for if foreseeability were the sole test we could not logically confine the extension of liability * * *" (*id.*, at 273, 445 N.Y.S.2d 108, 429 N.E.2d 786). The court also discussed three cases from other jurisdictions which recognized a cause of action for preconception tort, stating in relevant part (*id.*, at 274 n, 445 N.Y.S.2d 108, 429 N.E.2d 786):

> The third preconception tort case * * * (*Jorgensen v Meade Johnson Labs.*, 483 F2d 237 [(10 Cir.1973)], was decided on a products liability theory for which there is strict liability without fault. Under a products liability theory, once a defect in manufacture or design is established or there has been a failure to give adequate notice of foreseeable potential hazards, the liability of the manufacturer

> is extended to the entire class of persons thereby affected regardless of privity, foreseeability or due care (*Codling v. Paglia*, 32 NY2d 330 [345 N.Y.S.2d 461, 298 N.E.2d 622]). Accordingly, the necessity of establishing manageable bounds for liability is conspicuously absent.

Plaintiff contends that based upon the foregoing language, her strict products liability cause of action should be reinstated. Relying upon *Catherwood v. American Sterilizer Co.*, 130 Misc.2d 872, 498 N.Y.S.2d 703, *affd. on opn. below* 126 A.D.2d 978, 980, 511 N.Y.S.2d 805, 807, *appeal dismissed* 70 N.Y.2d 782, 521 N.Y.S.2d 222, 515 N.E.2d 908), defendants contend that New York does not recognize preconception strict products liability. In *Catherwood*, it was held that a child who was born with chromosomal damage, allegedly due to her mother's exposure to a toxic substance during the course of employment and prior to conception, had no cause of action. In so doing, the court concluded that although there may be no need for limitation on liability in most strict products liability cases, such a need exists in exposure and ingestion cases, relying largely upon the policy considerations underpinning the longstanding Statute of Limitations accrual rule which used the date of the injury, not the date of discovery (*id.*, at 874–875, 498 N.Y.S.2d 703). In *Fleishman v. Lilly & Co.*, 62 N.Y.2d 888, 890, 478 N.Y.S.2d 853, 467 N.E.2d 517), the

Court of Appeals refused to alter the old accrual rule and said, "Any departure from the policies underlying these well-established precedents is a matter for the Legislature and not the courts" (*id.*, at 890, 478 N.Y.S.2d 853, 467 N.E.2d 517). In 1986 the Legislature abandoned the old date-of-injury rule and adopted a rather complicated date-of-discovery rule for virtually all toxic torts (*see*, McLaughlin, Practice Commentaries, McKinney's Cons.Laws of N.Y., Book 7B, CPLR C214–c [1990 Supp.Pamph.], at 338–343). We are of the view that this legislative departure from the policies underlying the old rule raises considerable doubt as to the validity of Special Term's reasoning in *Catherwood v. American Sterilizer Co.*, *supra* which was based largely upon those policies.[2] Nevertheless, since this case is distinguishable on its facts, we need not decide whether to follow the holding in *Catherwood.*

The distinguishing factor is DES. In *Bichler v. Lilly & Co.*, 55 N.Y.2d 571, 579, 450 N.Y.S.2d 776, 436 N.E.2d 182, the Court of Appeals noted the large number of actions commenced "[i]n the wake of

2. In affirming for the reasons stated at Special Term, the Fourth Department said, "We add only that the legislative enactment of [CPLR 214–c], not in effect when the matter was before Special Term, does not change the result reached herein" (126 A.D.2d 978, 511 N.Y.S.2d 805). The two dissenting Justices in that case would recognize a preconception strict products liability cause of action due to the fundamental distinction between negligence and strict products liability (*id.*, at 979–980, 511 N.Y.S.2d 805).

knowledge about the devastation wrought by DES upon the female offspring of the several million pregnant women who ingested the drug over a 25–year period". While recognizing that some of those actions could be "prosecuted within well-established principles of products liability as those principles have been adapted to the manufacturing and marketing of prescription drugs" (*id.*), the *Bichler* court also said, "Products liability law cannot be expected to stand still where innocent victims face 'inordinately difficult problems of proof' * * *" (*id.*, at 579–580, 450 N.Y. S.2d 776, 436 N.E.2d 182, quoting *Caprara v. Chrysler Corp.*, 52 N.Y.2d 114, 123, 436 N.Y.S.2d 251, 417 N.E.2d 545).

The Legislature, too, has displayed substantial flexibility in affording DES victims a remedy. In addition to the aforementioned toxic tort Statute of Limitations (CPLR 214–c), the Legislature enacted a revival statute which opened a one-year "window" for actions for injuries caused by DES and four other toxic substances that were previously barred under the old date-of-injury rule (L.1986, ch. 682, § 4). Since plaintiff and other similarly situated infants already had the benefit of the tolling provisions of CPLR 208, the relevance to this case of the Legislature's enactment of the toxic tort statute, including the revival provision, lies in the clear manifestation of deep concern for those injured by toxic substances in general and DES in particular.

The most comprehensive statement of New York policy toward DES litigation can be found in *Hymowitz v. Lilly & Co.*, 73 N.Y.2d 487, 541 N.Y.S.2d 941, 539 N.E.2d 1069, *supra* wherein the Court of Appeals considered whether nonidentification of the manufacturer precludes recovery for DES-caused injuries and, if not, what theory of liability should be adopted. In resolving the relatively narrow issues under consideration, the court used the following broad unequivocal language to state New York policy (*id.*, at 507–508, 541 N.Y.S.2d 941, 539 N.E.2d 1069):

> Indeed, it would be inconsistent with the reasonable expectations of a modern society to say to these plaintiffs that because of the insidious nature of an injury that long remains dormant, and because so many manufacturers, each behind a curtain, contributed to the devastation, the cost of injury shall be borne by the innocent and not the wrongdoers. This is particularly so where the Legislature consciously created these expectations by reviving hundreds of DES cases. Consequently, the ever-evolving dictates of justice and fairness, which are the heart of our common-law system, require formation of a remedy for injuries caused by DES * * * (citations omitted).
>
> We stress, however, that the DES situation is a singular case, with manufacturers acting in a parallel manner to produce an identical, generically marketed product, which causes injury many years

later, and which has evoked a legislative response reviving previously barred actions.

Based upon this policy favoring a remedy for DES-caused injuries, and upon the conspicuous absence of the necessity of establishing manageable bounds for liability under a strict products liability theory (*Albala v. City of New York*, 54 N.Y.2d 269, 274 n, 445 N.Y.S.2d 108, 429 N.E.2d 786 *supra*), we hold that plaintiff has a cause of action in strict products liability for injuries caused by her mother's exposure to DES prior to plaintiff's conception. Although plaintiff is not a "DES daughter"—one who was exposed to DES while in utero—she may be no less a victim of the devastation wrought by DES than her mother, who is a DES daughter, and we see no sound basis for denying plaintiff her day in court along with her mother.

Our holding recognizes that plaintiff has a cause of action in strict products liability, a theory of liability adopted by the Court of Appeals in *Codling v. Paglia*, 32 N.Y.2d 330, 345 N.Y.S.2d 461, 298 N.E.2d 622, and a theory which is separate and distinct from liability based upon negligence (*see, e.g., Victorson v. Bock Laundry Mach. Co.*, 37 N.Y.2d 395, 400, 373 N.Y.S.2d 39, 335 N.E.2d 275). In so doing, we have resolved an issue of first impression in this court and one which the Court of Appeals plainly left open in *Albala v. City of New York, supra*, at 274 n, 445 N.Y.S.2d 108, 429 N.E.2d 786. Since plaintiff's allega-

tions are sufficient to meet the required elements of a strict products liability cause of action (*see, Codling v. Paglia, supra*, at 342, 345 N.Y.S.2d 461, 298 N.E.2d 622), we have sought "to strike the delicate balance between the competing policy considerations" required by the Court of Appeals in *Albala v. City of New York, supra*, at 275, 445 N.Y.S.2d 108, 429 N.E.2d 786. We recognize that there is room for rational disagreement with the balance we have achieved, but we have neither fashioned a new remedy out of sympathy nor overturned established legal principles. Nor does our recognition of a strict products liability cause of action in favor of plaintiff guarantee her success, for as plaintiff concedes, she bears the burden of proving all of the elements of a strict products liability cause of action, including the difficult question of proximate cause (*see, Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 110, 463 N.Y.S.2d 398, 450 N.E.2d 204). This burden, in our view, provides an adequate boundary of the manufacturers' legal responsibility for birth defects caused by DES. To insulate the drug manufacturers by creating an arbitrary generational limitation on the legal responsibility for birth defects caused by DES, thereby giving the manufacturers security in the knowledge that their liability will be limited to those exposed to DES in utero regardless of how many generations are actually injured by DES, would serve only to dilute the economic incentive to turn out safe products, which is the policy consideration most often

advanced for imposing strict liability upon the manufacturers of defective products regardless of privity, foreseeability or due care (*see, Sukljian v. Ross & Son Co.*, 69 N.Y.2d 89, 95, 511 N.Y.S.2d 821, 503 N.E.2d 1358).

WEISS, Justice (dissenting).

Of the several arguments initially presented in this appeal, we have been left with one issue of major dimension which appears to be of first impression for this court. Simply stated, the issue is whether liability based on the alleged use of a product during pregnancy can be extended to future generations of plaintiffs, not yet conceived, who themselves never had contact with the product. The majority, in what appears to me to be an example of judicial overreaching, has turned aside the established rule that New York does not recognize preconception tort liability under common-law negligence principles (*see, Albala v. City of New York*, 54 N.Y.2d 269, 445 N.Y.S.2d 108, 429 N.E.2d 786), then extracted selective portions from two cases grounded in strict products liability (*Bichler v. Lilly & Co.*, 55 N.Y.2d 571, 450 N.Y.S.2d 776, 436 N.E.2d 182 and *Hymowitz v. Lilly & Co.*, 73 N.Y.2d 487, 541 N.Y.S.2d 941, 539 N.E.2d 1069, *cert. denied* — U.S. ——, 110 S.Ct. 350, 107 L.Ed.2d 338), added the enactment of the revival statute creating a one-year "window" for actions for injuries allegedly caused by five toxic substances, including the drug die-

thylstilbestrol (hereinafter DES), all of which were previously barred under the date-of-injury rule (*see*, L.1986, ch. 682, § 4), and somehow arrived at the conclusion that plaintiff Karen Enright (hereinafter plaintiff), who never had contact with DES, has a cause of action in strict products liability because her grandmother allegedly ingested the drug while pregnant with plaintiff's mother. Put another way, plaintiff is a third-generation plaintiff alleging injuries resulting from her grandmother's ingestion of DES. I find no authority whatever in this State to support a cause of action for preconception tort in a third generation context for strict products liability. Because I believe the Justices of this court should not assume a legislative mode to fashion a new remedy for this alleged wrong, I respectfully dissent.

In *Albala v. City of New York*, *supra*, the Court of Appeals held that a tort committed against the mother of a child not yet conceived does not give rise to a cause of action in favor of that child for any injuries the child may suffer during its period of gestation attributable to the mother's injury before conceiving the child. In its refusal to extend a hospital's liability for medical malpractice in perforating the uterus during the mother's abortion so as to permit recovery by a child conceived four years after the alleged malpractice, the court held that recognition of such a cause of action under those circumstances would require the extension of traditional tort con-

cepts beyond manageable bounds. *Albala* remains the law in New York with respect to cases involving common-law negligence, including medical malpractice.[1]

In *Bichler v. Lilly & Co., supra*, a "DES daughter", i.e., one whose mother ingested DES during pregnancy, recovered damages for injuries she developed 17 years after her birth. In its affirmance, the Court of Appeals held that the trial court's instructions to the jury concerning the manufacturer's liability on a concerted action theory for injuries caused became the governing law of the case, no exception having been taken thereto, and that, in the light of those instructions, there was sufficient evidence to support the jury's verdict.[2] The prevailing plaintiff had directly come in contact with DES when the drug was in-

1. I disagree with plaintiff's contention that the footnote on page 274 in *Albala* can be seen as an unequivocal endorsement of preconception tort litigation in strict products liability cases. The three cases cited in the footnote are all foreign cases, two of which were found to be inapposite, and any reliance on the third held to be misplaced (*Albala v. City of New York*, 54 N.Y.2d 269, 274 n, 445 N.Y.S.2d 108, 429 N.E.2d 786, *supra*).

2. "Concerted action liability rests upon the principle that '[a]ll those who, in pursuance of a common plan or design to commit a tortious act, actively take part in it, or further it by cooperation or request, or who lend aid or encouragement to the wrongdoer, or ratify and adopt his acts done for their benefit, are equally liable with him'" (*Bichler v. Lilly & Co.*, 55 N.Y.2d 571, 580, 450 N.Y.S.2d 776, 436 N.E.2d 182, *supra*, quoting Prosser, Torts [4th ed], § 46, at 292).

gested by her mother during pregnancy.

After the *Bichler* decision, the Fourth Department affirmed a decision of Supreme Court in *Catherwood v. American Sterilizer Co.*, 126 A.D.2d 980, 511 N.Y.S.2d 807, *appeal dismissed* 70 N.Y.2d 782, 521 N.Y.S.2d 222, 515 N.E.2d 908), in which a mother was exposed to ethylene oxide prior to conception of a child subsequently born with chromosomal damage. In denying liability for genetic injury allegedly caused to the child, Supreme Court had found that the "policy need for limitation of liability in exposure and ingestion cases" called for the same result as in DES cases (*Catherwood v. American Sterilizer Co.*, 130 Misc.2d 872, 875, 498 N.Y.S.2d 703, *affd.* 126 A.D.2d 980, 511 N.Y.S.2d 807 *appeal dismissed* 70 N.Y.2d 782, 521 N.Y.S.2d 222, 515 N.E.2d 908).

Plaintiff has placed great emphasis upon certain of the language used by the Court of Appeals in *Hymowitz v. Lilly & Co.*, 73 N.Y.2d 487, 541 N.Y.S.2d 941, 539 N.E.2d 1069, *supra.* While it cannot be gainsaid that the court recognized the Draconian effects DES had upon those who used the drug and of the need for a remedy for those injuries (*id.*, at 507, 541 N.Y.S.2d 941, 539 N.E.2d 1069), the decision does not, as plaintiff would have us believe, either create a new cause of action in favor of third-generation DES plaintiffs or extend existing principles of strict products liability to such a class who themselves never came in

contact with the drug. The *Hymowitz* case decided two distinctly stated issues, and no more than those issues, namely: (1) the market-share theory of apportionment of liability among all manufacturers of DES is to be employed in New York, and (2) the revival statute, as it pertains to DES cases, has a rational basis and is constitutional. The issue of third-generation plaintiffs is not a part of that case and can have no role in this case. Indeed, the Court of Appeals explicitly stated that the Legislature's attention was specifically drawn to DES and that any change in the exposure rules was the role of the Legislature (*id.*, at 514, 541 N.Y.S.2d 941, 539 N.E.2d 1069, citing *Fleishman v. Lilly & Co.*, 62 N.Y.2d 888, 478 N.Y.S.2d 853, 467 N.E.2d 517, *cert. denied* 469 U.S. 1192, 105 S.Ct. 967, 83 L.Ed.2d 972), and further, that the "Legislature acted within its broad range of discretion in enacting the law" (*id.*, at 515, 541 N.Y.S.2d 941, 539 N.E.2d 1069). The case of *Fleishman v. Lilly & Co., supra* involved claims that cancer developed years after the use of DES, one by a direct user of the drug and the other by an in utero plaintiff exposed when her mother ingested DES. In affirming dismissal of both cases as time barred, the Court of Appeals refused to extend the Statute of Limitations for medical malpractice claims, stating that "[a]ny departure from the policies underlying these well-established precedents is a matter for the Legislature and not the courts" (*id.*, at 890, 478 N.Y.S.2d 853, 467 N.E.2d 517).

In its enactment of the toxic tort revival statute, the Legislature first defined "exposure" as any "direct or indirect exposure by absorption, contact, ingestion, inhalation or injection" (CPLR 214–c[1]). The operative effect of the statute is to revive every action for personal injury, injury to property or death "caused by the *latent effects of exposure* to [diethylstilbestrol] *upon or within the body*" which is time barred as of the effective date of the act and permit an action to be commenced within one year from the effective date of the act (CPLR 214–c[2], [3], [4] [emphasis supplied]). In *Besser v. Squibb & Sons*, 75 N.Y.2d 847, 552 N.Y.S.2d 923, 552 N.E.2d 171, *affg. on opn. below* 146 A.D.2d 107, 539 N.Y.S.2d 734), the Court of Appeals affirmed on the opinion of Justice Sullivan of the First Department.[3] The case speaks to exposure to DES *upon or within the body*. I believe the statute and *Besser v. Squibb & Sons supra* instruct that some direct contact between a plaintiff and DES must exist as a prerequisite to a cause of action under principles of strict products liability.

3. In *Besser v. Squibb & Sons (supra)*, the plaintiff's mother, a Pennsylvania resident, ingested DES 33 years earlier while she was pregnant with the plaintiff who became ill with cervical cancer at age 20 while residing in New Jersey. The issue in *Besser* was whether the toxic tort revival statute overcame the "borrowing statute" (CPLR 202) to permit the plaintiff who had no contacts with this State, save for maintaining residence here prior to commencing suit, to maintain suit against the drug manufacturer.

I perceive that defendants owed a duty to those who used DES, including those persons in utero at the time of such use. I fail to recognize a duty to generations not yet conceived who themselves would never come into contact with the drug. "While a court might impose a duty where none existed before, extreme care must always be exercised" in so doing (*Vogel v. West Mountain Corp.*, 97 A.D.2d 46, 49, 470 N.Y.S.2d 475; *see, Pulka v. Edelman*, 40 N.Y.2d 781, 786, 390 N.Y.S.2d 393, 358 N.E.2d 1019). "While the temptation is always great to provide a form of relief to one who has suffered, it is well established that the law cannot provide a remedy for every injury incurred * * *" (*Albala v. City of New York*, 54 N.Y.2d 269, 274, 445 N.Y.S.2d 108, 429 N.E.2d 786, *supra*, citing *Howard v. Lecher*, 42 N.Y.2d 109, 397 N.Y. S.2d 363, 366 N.E.2d 64). The tragic catastrophe engulfing plaintiff's life should neither tempt nor encourage judges to embrace a personal choice form of rationalization, "results-first, premises-to-follow" (Bork, The Tempting of America, at 264 [1990]). I find no indication, direct or by inference, demonstrating a legislative intent to extend the provisions of the statute to generations of plaintiffs who were unconceived at the time a forbearer was exposed to one of the five toxic substances in the statute.

For these reasons, I would affirm Supreme Court's order.

Order modified, on the law, with costs to plaintiffs, by reversing so much thereof as granted defendants' motions dismissing the third cause of action in the complaint; said motions denied and, as so modified, affirmed.

Opinion by CASEY, J.P., in which MIKOLL, YESAWICH and HARVEY, JJ., concur.

WEISS, J., dissents and votes to affirm in an opinion.

APPENDIX D—Opinion of the New York Supreme Court, Chenango County, September 28, 1988.

141 Misc.2d 194

Karen ENRIGHT, an infant under the age of 14 years old, by her mother and natural guardian, Patricia ENRIGHT, Patricia Enright, Ind., and Earl Enright, Ind., Plaintiffs,

v.

ELI LILLY & COMPANY, E.R. Squibb & Sons, Inc., Abbott Laboratories, the Upjohn Company, Merck & Company, Inc., and RXDC, Inc., formerly known as Rexall Corporation, formerly known as Rexall Drug Company, Defendants.

Supreme Court, Chenango County.

Sept. 28, 1988.

Child born with birth defects and her parents brought suit to recover damages from manufacturers of diethylstilbestrol. The Supreme Court, County of Chenango, Ingraham, J., held that: (1) child with handicaps whose grandmother ingested DES was not entitled to maintain cause of action against drug manufacturer for birth defects; (2) drug manufacturers were not entitled to summary judgment on mother's claim; (3) revival statute permitting late filing of DES claim was not unconstitutional; (4) revival statute did not permit derivative claim for loss of consortium; and (5) emotional claims resulting from birth of handicapped child are not cognizable.

Summary judgment denied in part; claims dismissed in part.

1. Drugs and Narcotics ⇐18

Cause of action against drug manufacturer for birth defects exists for child whose injuries occurred in utero as result of mother's drug ingestion.

2. Torts ⇐20

No cause of action exists for child conceived after tort injury to parent.

3. Drugs and Narcotics ⇐22

Plaintiff alleging injury from mother's ingestion of diethylstilbestrol could not maintain action in tort or products liability as a matter of law where plaintiff could not provide name of pharmacy, prescription, description of drug ingested by grandmother, name of pharmacist, or instructions for ingestion.

4. Products Liability ⇐73

Plaintiff alleging injury from use of specific substance must identify both specific substance and manufacturer thereof in order to state cause of action.

5. Drugs and Narcotics ⇐18

Plaintiff alleging injury from ingestion of drug by mother could not maintain cause of action on alternative liability theory or market share liability theory where plaintiff joined only limited number of potentially liable defendants.

6. Drugs and Narcotics ⇐18

Plaintiff alleging injury from mother's ingestion of diethylstilbestrol could maintain action against limited number of drug manufacturers under concerted action theory if plaintiff could establish that drug manufacturers acting jointly adopted common plan or design to commit tortious act or ratified common plan.

7. Judgment ⇐181(33)

Drug manufacturer which asserted that it could establish exculpation to concerted action theory was not entitled to summary judgment but, rather, was entitled to prove factual allegations of exculpation at trial.

8. Limitation of Actions ⇐6(9)

Exceptional circumstances must be demonstrated to warrant legislative intervention in reviving cause of action which is time barred.

9. Limitation of Actions ⇐6(9)

Injuries from ingestion of diethylstilbestrol which were undetectable until second generation constituted exceptional circumstances warranting legislative intervention in reviving cause of action which was time barred, and statute allowing claims did not violate constitution. U.S.C.A. Const.Amend. 14.

10. Limitation of Actions ⇐6(9)

Derivative loss of consortium claim is revived by statute reviving personal injury

action for claims arising out of latent effects of exposure to diethylstilbestrol.

11. **Damages** ⇐51

Parents of child born with birth defects due to grandmother's ingestion of diethylstilbestrol were not entitled to damages for emotional injuries resulting from birth of child.

Law Offices of Leonard L. Finz, P.C., Leonard L. Finz and Stuart L. Finz, New York City, for plaintiffs.

Law Offices of Russell H. Beatie, Sanford Berland, New York City, Greene, Hershdorfer & Sharpe, Lorraine M. Rann, Syracuse, for Eli Lilly & Co.

Phillips, Lytle, Hitchcock, Blaine & Huber, Tamar P. Halpern, Buffalo, for E.R. Squibb & Sons, Inc.

Patterson, Belknap, Webb & Tyler, Robert Wilson, New York City, for Abbott.

Bond, Schoeneck & King, John J. Dee, Syracuse, for Merck.

Winthrop, Stimson, Putnam & Roberts, A. Edward Grasof, New York City, for Rexall.

Sedgwick, Detert, Moran & Arnold, Nancy E. Gold, New York City, for the Upjohn Co.

IRAD S. INGRAHAM, Justice.

Plaintiffs bring suit to recover damages for personal injuries and related claims al-

legedly sustained as a consequence of ingestion of the drug diethylstilbestrol by Rosemary Whitmore Hickson, the mother of Plaintiff Patricia Enright and the grandmother of Plaintiff Karen Enright.

Defendants move for summary judgment dismissing the complaint for failure to state a cause of action and on the ground the claims are time barred together with various other grounds.

FACTUAL BACKGROUND

The drug diethylstilbestrol (DES) was invented more than fifty years ago and had been dispensed to women in the United States from 1941 to 1971. In 1947 the Federal Drug Administration approved the drug for treatment of complications relating to pregnancy. In 1971 its use was banned due to the link between its use and the later development of cancer in female offspring. Further history of the drug is unnecessary here as it has been cogently detailed in prior litigation. See *Bichler v. Eli Lilly & Co.*, 55 N.Y.2d 571, 450 N.Y.S. 2d 776, 436 N.E.2d 182.

In the instant case it is alleged that Rosemary Whitmore Hickson ingested DES "within the years 1959 and 1960". She gave birth to Plaintiff Patricia Enright on January 29, 1960. Patricia Enright gave birth to Plaintiff Karen Enright on August 9, 1981. It is alleged that Patricia Enright sustained a malformed uterus, cervical and uterine dysfunction and squamous metapla-

sia as a consequence of her mother's ingestion of DES. As a result of those injuries, it is alleged that Karen Enright was born prematurely and suffered cerebral palsy, grand mal seizures and various related congenital defects. In addition it is alleged that Patricia Enright suffered four spontaneous abortions before and after the birth of Karen Enright.

The exact dates of ingestion of DES by Rosemary Hickson, the names of the dispensing pharmacy and pharmacist, the prescription, the instructions for ingestion and the manufacturer of the drug ingested are all 'unknown' to Plaintiffs. Plaintiff's theory of liability as set forth in their complaint is: "If Plaintiffs are unable to identify the specific manufacturer and/or manufacturers of the specific DES ingested by Rosemary Whitmore Hickson same causing injuries as aforesaid to Plaintiffs herein, then Plaintiffs will rely on the theory of concerted action in that the Defendants, their agents, servants and/or employees, in pursuance of a common plan or design committed tortious acts as aforesaid in consciously paralleling each other, in failing to test and/or warn due to some implied understanding or defendants, their agents, servants, and/or employees, acting independently of each other, failed to properly test said DES, having the effect of substantially aiding or encouraging the failure to adequately test and warn by the others.

"Alternatively, Plaintiffs will rely on the theories of alternative liability, and/or en-

terprise liability, and/or market share liability."

Defendants, in moving to dismiss, emphasize that Plaintiff Karen Enright, conceived some 21 years after her grandmother's exposure to DES, has no cause of action under New York law. They further contend that without identification of the manufacturer of the drug ingested no liability can be posited. It is uncontroverted that DES was manufactured often generically by dozens of drug manufacturers. Defendants also claim the unconstitutionality of the revival statute under which Plaintiffs are permitted a late filing of their claims.

CONCLUSIONS OF LAW

From the voluminous documents filed and the myriad of issues therein raised, the following primary issues are distilled:

1. Does a granddaughter, born more than 20 years after the ingestion of drugs by her grandmother, have a cause of action against the drug manufacturer for birth defects claimed to have resulted from her mother's injuries which are linked to the drug ingestion?

2. Does New York recognize a joint theory of liability whereby all or any drug manufacturers of a harmful drug may be held responsible for injuries sustained from the drug regardless of whether they are identified as the manufacturer of the drug in the individual case?

3. Is the revival statute which permits the late filing of the instant lawsuit unconstitutional?

4. Does such revival statute permit a derivative claim for loss of consortium?

5. Are emotional claims resulting from the birth of a handicapped child cognizable in New York?

1. THE THIRD GENERATION CLAIM

[1, 2] Unquestionably a cause of action exists for a child whose injuries occurred in utero. *Woods v. Lancet*, 303 N.Y. 349, 102 N.E.2d 691. A cause of action does not exist for a child conceived after tort injury to the parent. *Albala v. City of New York*, 54 N.Y.2d 269, 445 N.Y.S.2d 108, 429 N.E.2d 786. Neither case considers the posture of Plaintiff Karen Enright. Patricia Enright's claim is for injuries occurring in utero. Karen Enright's cause of action is the claim of a child not in existence for injuries which resulted from injuries to a mother in utero, where the conduct complained of was directed to the grandmother. Clearly no parallel authority has been cited. To the extent, however, that *Albala* and *Catherwood* discuss "preconception tort in an exposure case," they are useful in furnishing instruction on policy considerations as well as the differentiation between tort liability and strict products liability cases. *Albala* supra; *Catherwood v. American Sterilizer*, 130 Misc.2d 872, 498 N.Y.S.2d 703, aff'd at 126 A.D.2d 980, 511 N.Y.S.2d 807.

Judge Wachtler, in the *Albala* case, outlined the policy considerations militating against the expansion of liability to pre-conception tort:

"We are of the opinion that the recognition of a cause of action under these circumstances would require the extension of traditional tort concepts beyond manageable bounds ..."

"... There is no predicate at common law or in our statutes for judicial recognition of the birth of a defective child as an injury to the child ..."

"We determined long ago in a case involving policy issues as sensitive as the ones at bar that foreseeability alone is not the hallmark of legal duty for if foreseeability were the sole test we could not logically confine the extension of liability." (cites omitted).

"Unlimited hypotheses accompanied by staggering implications are manifest. The perimeters of liability although a proper legislative concern, in cases such as these, cannot be judicially established in a reasonable and practical manner."

"While the temptation is always great to provide a form of relief to one who has suffered, it is well established that the law cannot provide a remedy for every injury incurred." (cite omitted) *Albala v. City of New York* at 271–274, 445 N.Y.S.2d 108, 429 N.E.2d 786 (supra). Judge Wachtler in a footnote distinguishes between tort liability and products liability. That distinction, although relied upon by Plaintiff here, was

held to be inapplicable to this type of case by the Appellate Division Fourth Department in the *Catherwood* case cited supra. Indeed, the theory of liability in this case becomes blurred of necessity when Plaintiff cannot identify the responsible drug manufacturer. The cause of action reverts to a tort claim when coupling all Defendants in a common plan to commit a tortious act, rather than relying upon a strict products liability cause of action.

Regardless of the label given to the cause of action, it would appear that the above policy considerations do apply. The *Jorgensen* and *Codling* cases referred to by Judge Wachtler are clearly distinguishable here. *Jorgensen v. Meade Johnson Labs,* 10 Cir., 483 F.2d 237; *Codling v. Paglia,* 32 N.Y.2d 330, 345 N.Y.S.2d 461, 298 N.E.2d 622. Certainly policy considerations which apply to second generation unconceived plaintiffs should be doubly applicable to third generation unconceived plaintiffs. Indeed it is doubtful that the legislature considered such an eventuality in opening the "window" (revival statute) for the late filing of DES claims.

The Assembly sponsor stated, "We picked the substances in this bill where we have an *identifiable* group of victims ... The Senate limited it to the five substances because they believe there was a *parameter of victims,* so there would be some insurance predictability." M.H. Miller June 24, 1986 (emphasis added) Certainly

in approving the measure, the Governor held a limited view of those entitled to sue.

"Most importantly, this measure remedies the injustices suffered by all of the *currently known categories of victims* of exposure to toxic or harmful substances. These include persons who have suffered serious injuries as a result of exposure to diethylstilbestrol ... and have been deprived of access to the courts because their claims were time barred." Governor's approval message July 30, 1986, 1986 McKinney's Session Laws of N.Y., at 3183 (emphasis added). The law itself, while not a model of clarity appears to be limiting:

> "... every action for personal injury ... caused by the latent effects of exposure to diethylstilbestrol ... *upon or within the body* ... which is barred as of the effective date of this act solely because the applicable period of limitations has ... expired is hereby revived ..." (L.1986, ch. 682, § 4; emphasis added.)

[3] Necessarily it is not for this court to determine the likelihood of Plaintiff's success should this action proceed. Rather, under a summary judgment review, it will be presumed that the facts set forth in the complaint are true. Karen Enright was born with severe congenital defects resulting from a premature birth. Her right to bring suit must now be determined by this Court as a matter of law. Her attorney asks this Court to cast liability backward two generations to a drug manufacturer.

Sympathies lie with the infant Plaintiff. Sympathies however cannot form the legal foundation for the pioneering decision sought by Plaintiffs. The practical considerations articulated by Judge Wachtler are perhaps nowhere so graphically illustrated as in this case. The Plaintiff's bill of particulars furnishes this insight. The Plaintiffs cannot provide the name of the pharmacy, the prescription, a physical description of the drug ingested by the grandmother, the name of the pharmacist, or the instructions for ingestion. Proceeding from such background, it must be assumed that Defendants will be equally unable to produce any definitive information for trial review. The passage of time and generations obscure such evidence to the extent that a third generation lawsuit must necessarily be posited solely upon sympathy and conjecture. Once all legal requirements of proof and rational limitations on the area of actionable causation are removed, the fact finding of the trial court will be severely impaired. There is no legal precedent for such liability. The precedent is to the contrary. That precedent is founded upon well reasoned considerations to which this Court subscribes.

The claims of the Plaintiff Karen Enright are dismissed as well as those claims of Patricia Enright and Earl Enright which are posited upon her claims. Specifically causes of actions # 1, 2, 3 and 4 are dismissed.

2. LIABILITY OF UNIDENTIFIED MANUFACTURER

[4] The general rule casts the burden of proof upon the Plaintiff to identify both the specific substance and the manufacturer thereof in order to state a cause of action. *Morrissey v. Conservative Gas Corp.*, 285 App.Div. 825, 136 N.Y.S.2d 844, aff'd 1 N.Y.2d 741, 152 N.Y.S.2d 289, 135 N.E.2d 45. The policy considerations for such rule have already been reviewed. Where a cause of action does exist however and the injury goes undetected, documented identification is impossible and where it is clear that the harmful product is manufactured in substantially the same form by a number of manufacturers, several jurisdictions have adopted theories to relieve the Plaintiff of its burden, and shift the identification problems to the manufacturers.

The Court of Appeals makes clear that none of the theories has received its imprimatur, although it affirmed a First Department ruling which applied the "concerted action" theory. *Kaufman v. Eli Lilly & Co.*, 65 N.Y.2d 449, 492 N.Y.S.2d 584, 482 N.E.2d 63; *Bichler v. Eli Lilly & Co.*, 79 A.D.2d 317, 436 N.Y.S.2d 625.

[5] Plaintiffs here tender a "shotgun" offense, relying in the alternative upon four different theories of unidentified manufacturer liability:

1) Concerted action
2) Alternative liability

3) Enterprise liability

4) Market share liability.

Several of these theories may be rejected outright. Plaintiffs have targeted six of the major drug companies, while it is conceded that upwards of one hundred manufactured DES and twelve were involved in a select committee to make recommendations to the Federal Drug Administration. Both the alternative liability and the market share liability theories are unavailable where Plaintiff elects to join only a limited number of the potentially liable Defendants. *Sindell v. Abbott*, 26 Cal.3d 588, 163 Cal.Rptr. 132, 607 P.2d 924; 22 A.L.R. 4th 183. The enterprise liability concept is described as a "hybrid derived from concepts of alternative and concurrent liability and the law of products liability to form a type of absolute liability." 22 A.L.R. 4th 185. It has been applied to DES cases, but not in New York.

The concerted action theory has been relied upon in cases tried in New York in the First and Second Departments. *Bichler v. Eli Lilly & Co.*, 79 A.D.2d 317, 436 N.Y.S. 2d 625; *Konopka v. Eli Lilly & Co.*, Nov. 19, 1987 (Nastasi, J.)

[6] The concerted action theory may be available to a plaintiff in spite of its targeting only a limited number of manufacturers as defendants. *Graphic Arts v. Bakers Mut. Ins.*, 45 N.Y.2d 551, 410 N.Y.S.2d 571, 382 N.E.2d 1347.

Where it can be established that defendants acting jointly adopt a common plan or design to commit a tortious act or ratify such a common plan, those injured thereby may hold any one of the defendants liable. *Bichler v. Eli Lilly & Co., supra.* Consequently it is the joint tortious activity of the manufacturers which gives rise to the cause of action.

"It does not strain one's sense of fairness to allow a limited expansion of the doctrine of concerted action to cover the type of circumstances faced in a DES case where the traditional evidentiary requirements of tort law may be insurmountable." *Bichler,* 79 A.D.2d at p. 329, 436 N.Y.S.2d 625.

Inexplicably the defendants did not actually contest the Plaintiff's concerted liability theory in *Bichler* by motion or exception to charge, resulting in a failure to preserve the issue for the Court of Appeals. Consequently the affirmance coupled with a later DES case formulated the ruling (or non ruling) that: "We expressed no view in *Bichler* and, express none now, on which of the proposed theories—concerted action, alternative liability, enterprise liability or market share liability—if any, should be adopted in this or similar DES cases (see *Bichler v. Eli Lilly & Co. supra* [55 N.Y.2d] at pg. 580 n. 5 [450 N.Y.S.2d 776, 436 N.E.2d 182]). The question is still an open one in New York." *Kaufman v. Eli Lilly & Co.,* 65 N.Y.2d 449, 456, 492 N.Y.S. 2d 584, 482 N.E.2d 63.

The compliance by the defendants here with the original Federal Drug Administration directive that they pool their information in 1941 unfortunately now forms the basis for the *Bichler* conclusion that the defendants acted jointly to commit a tort. The model then adopted set the pattern for later manufacturers. But factual matters do not come into play on this a motion for summary judgment. It is a legal issue which apparently has been ruled upon by the First Department. This Court feels that the same practical considerations which militate against extension of tort liability to third generation claims also militates against the concerted action theory of liability which in effect sanctions a lack of proof on plaintiff's part and shifts the burden of proof to defendants. The legal foundation for such a theory is lacking and the proponents are reduced to a Robin Hood logic of targeting the most prominent drug manufacturers to give to the unfortunate. However, the *Bichler* case at least at the Appellate Division level has spoken. It is incumbent upon this Court to follow such precedent, and accordingly the summary judgment motion on this basis must fail. *Mountain View Coach Lines v. Storms,* 102 A.D.2d 663, 476 N.Y.S.2d 918.

[7] Defendant RXDC asserts as a further defense to the concerted action theory, that it can establish exculpation. Clearly, where concerted action is an available remedy, a defendant who can establish that he was not the purveyor of the drug to a

particular plaintiff and did not act tortiously in concert with those which did, stands on different footing from his co-defendants. Exculpation, however, necessarily must rest upon proof of factual allegations. *Tique v. E.R. Squibb & Sons, Inc.*, 139 A.D.2d 431, 526 N.Y.S.2d 825.

This Court concludes that evidence may be adduced by defendants as to exculpation in defense of the concerted action theory, but a summary judgment does not lie in their favor prior to trial.

3. THE CONSTITUTIONALITY OF THE REVIVAL STATUTES

This issue has in general been dealt with by the courts. See *Agent Orange*, 597 F.Supp. 740; *Gallewski v. H. Hentz & Co.*, 301 N.Y. 164, 93 N.E.2d 620; *McCann v. Walsh Const. Co.*, 282 App.Div. 444, 123 N.Y.S.2d 509.

[8, 9] Exceptional circumstances must be demonstrated to warrant legislative intervention in reviving a cause of action which is time barred. Such circumstances have been documented in the legislative history of this enactment. It is obvious that the DES injuries are undetectable until the second generation and an exposure statute affords no remedy for the injuries sustained. Exceptional circumstances have been demonstrated and any claims based upon the unconstitutionality of the revival statute are denied.

4. REVIVAL OF DERIVATIVE CLAIMS

[10] The statute herein revives "every action for personal injury, injury to property ... caused by the latent effects of exposure to diethylstilbestrol ... upon or within the body." (L.1986, ch. 682, § 4.) Where the personal injury action is revived, the derivative loss of consortium claim is also revived. *Piccirelli v. Johns-Manville Sales Corp.*, 128 A.D.2d 762, 513 N.Y.S.2d 469.

While it is true that Patricia Enright brought her injuries to the marriage relationship, they were undiscoverable until child bearing. Accordingly the general tort rule is inapplicable, for the very purpose of the revival statute is to permit this type of litigation for an undiscoverable tort.

The complaint claims damages for Plaintiff Earl Enright alleging "that he will never have a healthy child."

The complaint claims damages for Plaintiff Patricia Enright alleging she "suffered emotional injury and distress due to her physical and emotional injuries as well as the physical and emotional injuries sustained by her daughter the infant Plaintiff Karen Enright."

[11] The claims of the parents insofar as they claim damages for emotional injuries resulting from the birth of their child are not cognizable under the laws of New York. *Howard v. Lecher*, 42 N.Y.2d 109,

113, 397 N.Y.S.2d 363, 366 N.E.2d 64; *Becker v. Schwartz*, 46 N.Y.2d 401, 413, 413 N.Y.S.2d 895, 386 N.E.2d 807; *Tobin v. Grossman*, 24 N.Y.2d 609, 301 N.Y.S.2d 554, 249 N.E.2d 419.

Accordingly cause of action # 7 insofar as it claims emotional injury as a result of the handicapped condition of Karen Enright is dismissed, and cause of action # 9 is dismissed.

APPENDIX E—Notice of Motion for Reargument for Leave to Appeal to the New York State Court of Appeals.

COURT OF APPEALS

STATE OF NEW YORK

KAREN ENRIGHT, an infant under the age of 14 years old, by her mother and natural guardian, PATRICIA ENRIGHT, and PATRICIA ENRIGHT, Individually and EARL ENRIGHT, Individually,

Plaintiffs,

against

ELI LILLY & COMPANY, E.R. SQUIBB & SONS, INC., ABBOTT LABORATORIES, THE UPJOHN COMPANY, MERCK & COMPANY, INC., AND RXDC, INC., formerly known as REXALL CORPORATION, formerly known as REXALL DRUG COMPANY,

Defendants.

SIRS:

PLEASE TAKE NOTICE, that upon the attached Brief of Respondent and the Order of the Court of Appeals made on February 19, 1991, dismissing the third cause of action on behalf of infant plaintiff, KAREN ENRIGHT, the undersigned will move this Court on the 1st day of April, 1 991,

or as soon thereafter as Counsel can be heard, for reargument, and upon such reargument, said plaintiff will move for an order reversing the February 19, 1991 Order of this Court upon the ground that the Points specified in the Brief appended hereto were overlooked or misapprehended, and for such other and further relief as may be just and proper.

Dated: New York, New York
March 18, 1991

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Court of Appeals

State of New York

KAREN ENRIGHT, an infant under the age of 14 years, by her mother and natural guardian, PATRICIA ENRIGHT, PATRICIA ENRIGHT, Individually and EARL ENRIGHT, Individually,

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Defendants.

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF KAREN ENRIGHT'S MOTION FOR REARGUMENT

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Table of Contents.

TABLE OF CASES AND AUTHORITIES.

Page

INTRODUCTION

Plaintiff KAREN ENRIGHT respectfully seeks reargument of this Court's decision in the above captioned case, dated February 19, 1991 (hereinafter *"Enright"),* pursuant to 22 NYCRR 500.1 1 (g).

It is most respectfully submitted that the Court did not consider the strict products liability/*design defect* cause of action, in Plaintiffs' Complaint, and *only* considered the "failure to warn" theory. A strict products liability/*design defect* theory has policy implications which distinguish it from *Albala v. New York,* 54 N.Y.2d 269, 445 N.Y.S.2d 108 (1981)—the main precedent upon which this Court relied in deciding *Enright.* The social consequences of *Enright,* require that the public policy issues applicable to a strict products liability/*design defect* cause of action be reconsidered by this Court—and upon such reconsideration, that the Court's decision in *Enright* be redefined so as to recognize the validity of plaintiffs' strict products liability/*design defect* cause of action as distinguished from a "failure to warn" cause of action which is rooted in negligence.

Further, it is most respectfully submitted that this *Honorable Court's decision transcends constitutionally permissible bounds, and should be reconsidered for this reason as well.

POINT I

THIS COURT DID NOT CONSIDER KAREN ENRIGHT'S STRICT PRODUCTS LIABILITY/*DESIGN DEFECT* CAUSE OF ACTION:

A. THE ENRIGHT'S CLAIMS INCLUDE A STRICT PRODUCTS LIABILITY/*DESIGN DEFECT* CAUSE OF ACTION.

The *Enright* case presents a strict products liability/*design defect* cause of action which distinguishes it from the *Albala v. New York*, precedent, upon which this Court relied.[1] The strict products liability/*design defect* allegations are contained in the third cause of action in the complaint (R. 136-137).

It is respectfully submitted that the Court treated the *Enright* case as though it was brought ***solely*** on a "failure to warn" theory, and decided it accordingly. On page 13-14, decision, the Court stated:

> [Als in most prescription drug cases *(see, D. Vinson & A. Slaughter, Products Liability: Pharmaceuti-*

[1]For the purposes of this motion and the underlying appeal, the Court should accept as true the allegations and theories propounded by the plaintiff; that is, assume that there is in fact a design defect in the DES product. That being assumed, plaintiff presents an entirely different legal concept to the Court, replete with wholly differing policy implications, than what the Court considered in its prior decision.

Whether a design defect exists in a particular product is for the jury to answer, *Voss v. Black & Decker Manufacturing Co.*, 59 N.Y.2d 102, 108-109, 463 N.Y.S.2d 398, 401-402 (1983); *Rainbow v. Elia Bldg. Co., 79 A.D.2d 287, 291, 436 N.Y.S.2d 480, 484-485, aff'd. 56 N.Y.2d 550, 449 N.Y.S.2d 967 (1982); Robinson v. Reed-Prentice Div. of Package Mach. Co.* 49 N.Y.2d 471, 478-479, 426 N.Y.S.2d 717, 719-720 (1980); *Micallef v. Miehle Co., Div. of Miehle-Gross Dexter* 39 N.Y.2d 376, 384 N.Y.S.2d 115 (1976), after application of a risk/utility test, *Cover v. Cohen*, 61 N.Y.2d 261, 473 N.Y.S.2d 378 (1984); *Voss v. Black & Decker, supra, Robinson, supra.*

> *cal Drug Cases, at 123-140), liability here is predicated on a failure to warn* of dangers of which the manufacturers knew or with adequate testing should have known. [Emphasis ours.]

The Court's language categorizes this case as being premised *solely* on a "failure to warn" theory, which it is not.[2]

Enright presents a valid cause of action based upon strict products liability/*design defect.* [3]This theory was not considered by the Court previously. Plaintiff submits that the implications of a strict products liability/*design defect* theory presents a sound basis upon which to distinguish *Albala v. New York, supra.*

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[2]The learned treatise which the Court cited was written by the same attorneys who for 15 years have been trial counsel to the largest DES manufacturer—Eli Lilly & Co., Inc. *Vinson, supra,* at page xii.

As such, that treatise has its own reasons to summarily categorize all DES claims simply as "failure to warn" cases, since that theory may well be the easiest for the DES defense bar to defeat.

[3]Many courts have recognized the validity of a design defect cause of action for the improper "design" of prescription drugs. *Jones v. Lederle Laboratories,* 695, F.Supp. 700 (E.D.N.Y. 1988), accord, *Castrigano v. E.R. Squibb & Sons,* 546 A.2d. 775 (R.I. 1988) (Recognizing validity of defective design theory in "DES" case). Further supporting authority is found in *Brochu v. Ortho Pharmaceutical Corp.,* 64 F.2d 652 (1st Cir. 1981); *Ortho Pharmaceuticals Corp. v. Health,* 722 P.2d. 410 (Colo. 1986) *(en banc); Graham v. Wyeth Laboratories,* 666 F.Supp. 1483 (D. Kan. 1987); *Toner v. Lederle Laboratories,* 1 1 2 Idaho 328, 732 P.2d. 297 (1984), as conformed to *Toner v. Lederle Laboratories,* 828 F.2d 510 (9th Cir. 1987), *cert. denied,* 108 S. Ct. 1122 (1988); *Kociemba v. G.D. Searle & Co., 695 F. Supp. 432 (D. Minn. 1988); Coursen v. A.H. Robbins Co. Inc.,* 764 F.2d 1329 (9th Cir. 1985); *Pollard v. Ashby,* 793 S.W.2d 394 (Mo. App. 1990) *(en banc).*

Moreover, the *Enright* decision is sufficiently broad in scope to determine the rights of victims in all product liability suits, many of which will include defective design claims.

B. A STRICT PRODUCTS LIABILITY/*DESIGN DEFECT* CAUSE OF ACTION IS NOT LIMITED BASED UPON THE RELATIONSHIP OF THE PARTIES, OR WHETHER THE PLAINTIFF HAD DIRECT CONTACT WITH DEFENDANT'S PRODUCT

The Court in *Enright* stated a fundamental inquiry: whether the fact that *Enright* is based on strict products liability rather than negligence serves to distinguish it from *Albala v. New York, supra.* The Court, focusing on the strict products liability "failure to warn" theory, found that in the context of this case, these theories were indistinguishable because:

> [i]n neither this case nor *Albala* was the infant plaintiff exposed to the defendants' dangerous product or negligent conduct....

Opinion at p. 15. It is respectfully submitted that while plaintiff's lack of direct contact or exposure to the product is a proper basis for dismissal based upon negligence and strict products liability "failure to warn" theories, which theories have historically limited liability based upon the relationship of the plaintiff and the defendant (in accordance with the prior decisions of this Court), it is not a proper basis for dismissal based upon a strict products liability/design defect cause of action.

With regard to causes of action rooted in negligence, rules of circumscription based upon public policy considerations, which often focus on the relationship of the plaintiff and the defendant, such as those propounded by this Court in *Enright,* abound. *See,* e.g., *Pulka v. Edelman,* 40 N.Y.2d 781, 390 N.Y.S.2d 393 (1976). By contrast, this Court has not so limited the strict products liability/*design defect* cause of action. From the initial recognition of the

strict products liability/*design defect* theory in New York by this Court, its great distinction was the creation of liability without regard to the nature of the relationship between the plaintiff and the defendant, based upon the public policy determination that the costs for injuries caused by the product should be borne by the manufacturer, rather than the injured plaintiff. *Codling v. Paglia,* 32 N.Y.2d 330, 345 N.Y.S.2d 461 (1973). Those venerable principles have full applicability in the context of a strict products liability/*design defect* cause of action in this case. Indeed, the applicability of those policy considerations cannot be overstated with the question being whether to place the risks, costs and burdens of these terrible injuries upon the innocent plaintiffs, who have no ability to absorb them, or upon the manufacturing entities which caused the injuries. The importance of facing this choice (either the plaintiffs or the defendants will bear the burdens) in the context of a strict products liability/*design defect* theory is paramount if the class of injured plaintiffs affected by *Enright* is as large as defendants' claim.

The principles set forth in, *Codlinq v. Paglia, supra,* are the foundation upon which this Court based its decision in *Sage v. Fairchild-Swearinger Corp.,* 126 A.D.2d 914, 511 N.Y.S.2d 432, *reversed,* 70 N.Y.2d 579, 523 N.Y.S.2d 418 (1987). In *Sage v. Fairchild, supra,* this Court held defendant liable on a strict products liability/*design defect* theory in the absence of any physical contact between the plaintiff and the defendant manufacturer's product, where a third party had replicated defendant's product.[4] It was the replication which caused the injury.

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[4]The Appellate Division found that the "copy" was not substantially the same as the original in that "[t]he measurement were not the same and the replacement lacked other features of the original." 511 N.Y.S.2d at 434.

The Appellate division held that allowing recovery:

> would expand the scope of a manufacturers duty beyond all reasonable bounds and would be tantamount to imposing absolute liability on manufacturers for all product related injuries ....

511 N.Y.S.2d at 434. This Court rejected the Appellate Division's conclusion, and found that the defendant was liable for all foreseeable injuries because it placed the product and the *design* in the stream of commerce.

Sage v. Fairchild, supra, rested squarely on the principles established in *Codling v. Paglia, supra* - that a manufacturer is responsible for the foreseeable consequences of having placed a *defective product* in the stream of commerce, regardless of the relationship between the plaintiff and the defendant, and therefore, regardless of whether the manufacturer's product directly or indirectly caused injury. The Court in *Sage v. Fairchild, supra,* was not moved by claims of "unmanageable bounds" or "absolute liability". The Court refused to stray from the well-established balances which underpin the strict products liability/*design defect* cause of action. It is respectfully submitted that with regard to plaintiffs strict products liability/*design defect* cause of action, there is no reason for a different decision here.[5]

Moreover, *Albala v. New York, supra,* sought to extend recovery to an injured plaintiff in a medical malpractice (negligence) context. The legislature has consistently

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[5]The accrual rules in defective design cases have long recognized that the legal genesis or accrual of these causes of action are based upon factors unrelated to contact between the product and the plaintiff. *See,* e.g. *Martin v. Edwards Laboratories, Division of American Hospital Supply Corp.,* 60 N.Y.2d 417, 469 N.Y.S.2d 923. The specific finding of direct contact has never been the definitional equivalent or determinant of the existence of a defective design cause of action.

endeavored to halt the expansion of medical malpractice litigation and limit medical malpractice claimants' rights to recover, both explicitly and implicitly, in a series of "tort reforms" addressing the socalled "medical malpractice crises" of the mid-seventies and eighties.[6]

In contrast, there has been no new legislation over the past decades designed to limit strict products liability/*design defect* cases. Thus, *the explicit legislative design in reducing malpractice liability evidenced in these statutory revisions, and further implemented in Albala is absent here.*[7]

The role *Codling v. Paglia, supra,* has played in the formation of New York jurisprudence is unequaled. For the past seventeen years, *Codlinq v. Paglia, supra,* has been the cornerstone of strict products liability law in New York. Strict products liability has developed *independent* of common law negligence. Its principles have often provided plaintiffs with avenues of recovery unavailable under negligence law. It is most respectfully submitted that in deciding Enright, the Court did not consider the strict products liability/*design defect* cause of action and its underlying

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[6]See, for instance, the bill jackets and cases discussing the legislative intent surrounding CPLR 3012(a) (requirement of a Certificate of Merit); P.H.L. 2805-m(3) and CPLR 3045 (compulsory arbitration on damages at the defendants' election, in return for a concession of liability); Judiciary Law 474-a (reduced contingency fees in malpractice cases); CPLR 50-A (structured judgment in malpractice actions); CPLR 4546 (offsets against lost earnings claims in malpractice actions); CPLR 4545(a) (collateral source offsets in malpractice claims); Judiciary Law 148-a (malpractice panel requirements); CPLR 214-a (reduced statute of limitations for malpractice claims); etc.

[7]In specific contr-distinction to the legislature's actions relative to *Albala* and the malpractice arena, various statutes have been enacted in the strict products liability/design defect field which *enlarge* rather than restrict the victim's access to the courts. Not the least significant in this area is the enabling legislation which resurrected all of the otherwise time-barred DES cases: New York's toxic tort revival legislation, the Omnibus Tort Reform Act, L. 1986, Ch.682.

principles, as distinguished from a "failure to warn" cause of action which is rooted in negligence.

POINT II

THE ENRIGHT DECISION RAISES CONSTITUTIONAL CONCERNS OF EQUAL PROTECTION AND DUE PROCESS[8]

A. THE ENRIGHT DECISION DENIES A CLASS OF PLAINTIFFS THE RIGHT OF ACCESS TO OUR COURTS

It is most respectfully submitted that the Enright decision has the effect of denying an entire class of plaintiffs the right of access to our Courts.[9]

Enright focused on two factors as a basis for denying a class of plaintiffs access to our Courts:

a. "The nature of plaintiffs' injuries . . .—birth defects"

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[8]Although reargument is generally limited to issues "overlooked or misapprehended by the Court," NYCRR 500.1 1 (g)(3) explicitly provides the right to raise points for the first time "for extraordinary and compelling reasons." Plaintiff respectfully submits that the need for judicial review of the equal protection and due process concerns (which were implicity raised and discussed by both the majority and dissent, See Opinion at pg. 1 5, and See Dissent at pg. 1 2), establish "extraordinary and compelling reasons" thus justifying their being explicitly raised by plaintiff herein.

[9]The Court's decision has the effect of denying the right of access to our Courts to all preconception tort victims, (treating them dissimilarly to all other tort victims), thus, the Court's focus on the nature of the injury, and on its concerns particular to the pharmaceutical industry, as a basis for denying access to our Courts, raises a constitutional issue as these concerns are unrelated to many potential preconception tort cases.

b. "and their cause—harm to the mothers' reproductive systems before the children were conceived...."

Id. at p. 12. It is respectfully submitted that neither factor provides a sound constitutional basis for denying Karen Enright and all those similarly situated, equal protection of the law.

It is acknowledged that the Court sought to limit the aggregate verdict amounts against the pharmaceutical industry because of the concern as to the continued viability of that industry. This method of limiting aggregate verdict amounts against the pharmaceutical industry, however, denies the right of access to our Courts to those victims who are most severely injured.

Further, plaintiff respectfully submits that the denial of access to our Courts to a class of plaintiffs based upon the "cause of the injuries", raises constitutional concerns. The Court has accepted, for the purposes before it, that plaintiff Karen Enright was rendered severely brain-damaged as a direct result of defendants' marketing of a defectively *designed* drug, and that plaintiff may be able to substantiate that claim through competent scientific evidence. It is respectfully submitted that the specific manner in which a defective product works its harm does not provide a constitutional basis for distinguishing the class to which plaintiff belongs. Instead, it results in the drawing of an arbitrary line for the purpose of "confin[ing] liability..." Id. at p. 13.[10]

[10]The distinction set forth by the Court apparently gives all of the following greater rights than the class to which plaintiff belongs: (1) those plaintiffs who suffer the results of immediate temporal contact with a defective product; (2) those plaintiffs who were *in utero* at the time of their mother's contact with a defective product; and (3) those plaintiffs who were not conceived at the time of their mother's direct temporal contact with a defective product, but whose injuries were caused by factors other than injury to their mother's reproductive system.

In addition, the *Enright* decision will result in *complete immunity* from liability to those manufacturers whose defective products only work their harm on a generation not conceived.

B. THE RECORD BEFORE THE COURT DOES NOT SUPPORT THE NEED TO GIVE THE PHARMEUCEUTICAL INDUSTRY SPECIAL PROTECTION

Plaintiff respectfully submits that the decision has the effect of granting special protection to the pharmaceutical industry. It is further submitted that based on the desire to avoid "overdeterrance" to the pharmaceutical industry, the decision effectively denied an entire class of injured plaintiffs (the class being much broader than those injured by this particular industry, *see,* footnote 9. *infra)* the right of access to our Courts.

Plaintiff respectfully submits that the availability of laws to compensate victims of *defective* products placed on the market by the pharmaceutical industry is a matter of continuing legislative activity both on the state and the federal level. The New York State Legislature has engaged in years of debate and policy-making with regard to remedies which should be available, particularly to DES victims. The record before this Court is devoid of any evidence that the legislature accepted the industry's purported concern that it would be driven out of business or that it would stop producing products because of potential liability. Rather, it is submitted that the legislature, after years of debate, strongly indicated that the policy of this state favors that access to our Courts be permitted to DES victims—and Karen Enright falls within that class.

Furthermore, there is no evidentiary record in this case which supports the pharmaceutical industry's purported

concern that the public would be harmed by allowing recovery in these cases. There has been no discovery on this subject. There has been no depositions with the right of cross-examination to explore the pharmaceutical industry's claim. There has been no document production relative to the impact upon the pharmaceutical industry resulting from its potential liability. There has only been the self serving commentary of the defendants themselves.

C. THE COURT'S BROAD CONCERN WITH LIMITING LIABILITYTO MANAGEABLE BOUNDS DOES NOT PROVIDE A CONSTITUTIONAL BASIS FOR DENYING A CLASS OF PLAINTIFFS ACCESS TO OUR COURTS

It is most respectfully submitted that in order to deny a class equal protection of the law, there must be a "rational basis" for doing so. The Court's stated rationale that it must "confine liability within manageable limits," Id. at p. 13, does not, in this context, provide such a "rational basis."

CONCLUSION

It is most respectfully submitted that the Court did not consider the strict products liability/*design defect* cause of action, in Plaintiffs' Complaint, and *only* considered the "failure to warn" theory, the implications of which may turn back New York strict products liability jurisprudence to pre-*Codling* days. The principals which were set forth in *Codling,* should be applied. A strict products liability/*design defect* theory has policy implications which distinguish it from *Albala v. New York, supra,*—the main precedent upon which this Court relied in deciding *Enright.* The consequences of *Enright* require that the public policy issues applicable to a strict products liability/*design defect* cause of action, be reconsidered by this Court—and upon such

reconsideration, that the Court's decision in *Enright* be redefined so as to recognize the validity of plaintiff's strict products liability/*design defect* cause of action as distinguished from a "failure to warn" cause of action, which is rooted in negligence.

Further, it is most respectfully submitted that the *Enright* decision transcends constitutionally permissible bounds, and should be reconsidered for this reason as well.

Dated: New York, New York
March 18, 1991

Respectfully submitted,

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